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The Pan-European Organisation of Personal Injury Lawyers

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PERSONAL INJURY LITIGATION IN THE DIGITAL AGE

LIABILITIES, COMPENSATION AND INSURANCE FOR PERSONAL INJURY AND DEATH BETWEEN TRADITIONAL PRODUCTS, DIGITAL DIMENSIONS AND ARTIFICIAL INTELLIGENCE

THE FUTURE PROTECTION OF VICTIMS IN THE EU

PEOPIL POSITION PAPER ON THE REVISION OF THE PRODUCT LIABILITY DIRECTIVE AND THE PROPOSAL FOR THE AI LIABILITY DIRECTIVE

- January 2024 -

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I. BACKGROUND, SCOPE, CONTENTS AND BASIC PRINCIPLES OF THIS POSITION PAPER.

1. PEOPIL, as a leading European organisation of personal injury lawyers and academics, is devoted to the study of European law and to the development of a full and fair protection of injured persons without any frontiers between European jurisdictions.
2. PEOPIL is extremely concerned about the potential damaging effects that traditional products and the new technologies may develop in the years to come, this both in the light of the "digital revolution" that is taking place in all sectors and the explosion of the AI systems.
3. PEOPIL is pleased to have participated in various committees and consultations that led to the two proposals, both dated 28 September 2022, by the European Commission for the revision of the Product Liability Directive [***Proposal for a Directive of the European Parliament and of the Council on liability for defective products***[1], hereinafter also the "**PLD Proposal**"], which is going through the ordinary legislative **Procedure 2022/0302/COD** 2, and the ***Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)***[3], hereinafter the "**AILD Proposal**", at the moment of presenting this paper subject to the ordinary legislative **Procedure 2022/0303/COD**.
4. Both these historical proposals, that are analysed in this paper, address the need for the adaptation of liability rules to the digital world by either revising the already existing uniform rules provided by the 1985 Product Liability Directive and formulating new schemes for operators and users of the new emerging technologies including AI systems.
5. PEOPIL already intervened in relation to both the interconnected matters covered by the above proposals with the following papers available at *www.peopil.com*:
   - ***PEOPIL Submissions on the Product Liability Directive Guidance*** (**October 2018**);
   - ***Response to the EU Consultation on artificial intelligence liability and insurance for personal injury and death damages caused by ai artefacts/systems*** (**September**

[1] COM(2022) 495 final.

[2] In this paper we consider either the original draft by the European Commission and the amended version proposed by Report on the proposal for a directive of the European Parliament and of the Council on liability for defective products (COM(2022)0495 – C9-0322/2022 – 2022/0302(COD)) approved by the Committee on the Internal Market and Consumer Protection Committee on Legal Affairs (Rapporteurs: Pascal Arimont, Vlad-Marius Botoş) on 12 October 2023 (A9-0291/2023), hereinafter referred to as the "**12.11.2023 Parliament's PLD version**".

[3] COM(2022) 496 final.

2020), which focused on the European Commission's White Paper entitled «*On Artificial Intelligence – A European approach to excellence and trust*», and, in particular, the *Report from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the safety and liability implications of Artificial Intelligence (AI), the Internet of Things and robotics* [both dated 19 February 2020 (respectively COM(2020) 65 final and COM(2020) 64 final];

- ***PEOPIL Response to the planned revised Product Liability Directive*** (**December 2022**).

6. Moreover, at the 9th October 2020 workshop "AI and liability" at the Second European AI Alliance Assembly, a stakeholder event organized by the European Commission, key to the Commission's policymaking process in the field of AI, PEOPIL expressed some positive remarks on the draft that led to the ***European Parliament resolution of 20 October 2020 with recommendations to the Commission on a Civil liability regime for artificial intelligence (2020/2014(INL))***[4], hereinafter the "**Parliament AIL Proposal**" (**Procedure 2021/0106/COD**)[5], while outlining critical issues in relation to the distinction between "high-risk" AI systems and "low-risk" AI systems (the latter excluded from the operational scope of the proposed directive) and to the recommended rules on the compensation for damages arising from personal injury and death cases.
7. In order to properly address these scenarios of potential new rules affecting liability and compensation for personal injury, death and other violations of fundamental rights PEOPIL set up a special team composed of the PEOPIL members already committed to this topic as well as new members practising in the area of product liability and technologies (the so-called "**PEOPIL Tort Reform Group**").
8. The group met 7 times between 2023 and 2024. The first meeting took place at Girona University on 6th of July 2023. The second meeting was held in Dublin in person at the time of PEOPIL Annual Conference and from remote on 28th September, followed by a third meeting by video conference on 23rd October. The fourth meeting took place in Malaga both in person and from remote on the 3rd November. The final three meetings took place from remote on 24th November 2003, 27th December 2023 and 15th January 2024. In between the above meetings the group intensively exchanged opinions and suggestions working on an online draft of this paper.
9. The first outcome of the debate inside this group and the above meetings, is this paper in which PEOPIL focus on the following issues:
   - the European Commission's proposal for the revision of the Product Liability Directive ("PLD Proposal"): whilst PEOPIL welcomes the recognition that the present 1985 directive requires updating and is unsatisfactory for victims' protection in several parts, it is at least partially disappointed with the 28th of September 2022 draft and the subsequent versions. PEOPIL consider that, despite some positive proposals, the future new directive continues to fail all those seeking redress of any damage sustained, particularly in terms of substantive and procedural remedies available to them when accidents occur;

[4] In particular, a positive view was expressed in relation to the proposed provision under which the operator of a high-risk AI-system shall be strictly liable for any harm or damage that was caused by a physical or virtual activity, device or process driven by that AI-system [see Article 4 (1) of the PLD proposal).

[5] The European Parliament adopted this legislative own-initiative resolution on the ground of Article 225 TFEU and requested the Commission to propose legislation.

- the potential scenarios, in addition to the revised Product Liability Directive, for an EU liability regime or different regimes designed to grant protection to personal injury or fatal accident victims due to the operation/use of AI artefacts/systems: in this regard PEOPIL support the introduction of a specific strict liability regime (or cause of action) or, alternatively, a system for a reversal of the burden of proof/presumptions in relation to either fault and causation for personal injury and death arising from the operation/use of AI artefacts/systems; it appears that the above proposal for a "AI Liability Directive" ("AILD Proposal") can be much improved in relation to various aspects, including pre-trial discovery, reversal of the burden of proof and minimum rules on limitation law;
- the harmonisation of the rules on compensation for damages: according to its consolidated positions and due to the ongoing divergences among Member States PEOPIL oppose any provision aiming at the maximum approximation of the national laws on damages, unless the proposed rules provide - in relation to heads of damages, recoverable losses, *quantum* of awards, entitlement to claim for damages - etc., the highest standard rules towards full compensation, which is not the case of the proposals here under scrutiny;
- possible EU uniform provisions of insurance coverage for such accidents and damages;
- possible role of a harmonized regime of disclosure of evidence.

10. Our **basic principles** transversal to all above issues are:
    - uniform rules on liability, compensation, insurance and evidence should be designed by EU legislator in favour of the victims and with the aim of granting them the right to full and fair compensation;
    - strict liability regimes based on rules on presumptions and reversal of the burden of proof significantly shifting the *onus probandi* concerning the grounds of liability (first of all causation) from the claimants to the professional defendants should be the model ("plan A") to be preferred and adopted in order to promote prevention and victims' protection;
    - there should not be any compromise on the protection of fundamental rights.
11. In particular, to this last respect in the case of infringement to life/health and of the other fundamental human rights, the arguments in support of an ineluctable "compromise" between the need to protect the rights of the individuals on one hand and the financial interests of the industry, or even the need to facilitate and not discourage technology development on the other hand, cannot be accepted and contradict the basic principles of the European legal system and values. These fundamental human rights are to be protected and safeguarded against any harm or infringement. Encouragement of the AI development and protection of the viability of its developers can only be permitted if the fundamental human rights are previously ensured fair protection.
12. It is very doubtful whether the AI Act and the two proposed directives here under examination, however carefully and fairly designed and drafted, will ever succeed in ensuring the above protection of fundamental human rights and the prevention of related damages, this also in view of the global impact of AI systems in a digitalized world. However, by the imposition of strict liability and 'consequences' on the AI developers in case the AI systems inflict damage to fundamental human right, a level of 'self-regulation' may be achieved, where the AI developers and users, whether EU or other, will do their best to take all measures in order to avoid exposure to stringent consequences under EU law. Maybe this is the only way to

achieve a good level of safety from AI and more in general the products of the "digital revolution", and at the same time to avoid over-regulation, which shall always be out-dated in view of the speed of developments in technology.

13. We know that the EU Institutions will receive loud submissions from those asserting that directives like the PLD and AILD will have a chilling effect on innovation and business. The EU should explicitly apply the precautionary principle to AI systems and new technologies as it does to environmental law (see Art. 191 TFEU).
14. The drafting of specific harmonized rules for the EU reviewing the old product liability directive and introducing new liability regimes for products and services typical of the "digital age", including AI systems, clearly attracts opposite groups of stakeholders with different capabilities in the way they can impact on the future provisions. The ones who govern the economy and the tech sector have of course all the resources to influence the path leading to new legislative assets. Citizens at risk of becoming victims of traditional, new and futuristic products/services have much lower powers in this process. The imbalance between the two categories of lobbyists is huge, as also demonstrated by the entities who provided inputs to the two rapporteurs of the European Parliament's Committee on the Internal Market and Consumer protection and the Committee of Legal Affairs that delivered the Draft Report on the "PLD Proposal" on 5th April 2023 and the "12.11.2023 Parliament's PLD version" (apart from three Member States and a consumer organization, the list is composed for the vast majority by insurance companies, multinationals like Google, eBay and Amazon, representatives and associations of the industry). With this paper PEOPIL aim to contribute to rectify such gap, even if modestly.
15. Finally, at the time of completing this report (January 2024) the following developments have intervened in the EU legislative process towards new sets of harmonised rules affecting the areas here under examination:
    - on 9th December 2023 the Council presidency and the European Parliament's negotiators reached a provisional agreement on the proposal on harmonised rules on artificial intelligence (AI), more specifically the ***Proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts*** (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)), advanced by the European Commission on 21 April 2021 (hereinafter the "**AI Act**");
    - on 14th December 2023 the European Parliament and the Council reached a provisional agreement on the proposal for the new Product Liability Directive.
16. At the beginning of 2024 the new rules remain to be formally adopted by the European Parliament and the Council. Moreover, once approved, the new Product Liability Directive, which is still at its first reading before the European Parliament, shall be transposed into Member States' national law. Accordingly, we are aware that some comments and suggestions in this report - in particular those related to the future new PLD - may arrive too late for contributing to the EU legislative process. However, they shall constitute the basis for further PEOPIL initiatives towards higher standards of protection of victims both at the European (EU and Council of Europe) level and the national level in relation to the transposition of the new rules.

II. INTRODUCTION TO THE PENDING PROPOSALS IN THE EU: GENERAL FEATURES.

17. The Commission's proposal for a Directive on adapting non-contractual liability rules to artificial intelligence ("**AILD Proposal**") aims to establish common rules on (a) the disclosure of evidence on high-risk artificial intelligence (AI) systems to enable a claimant to substantiate a non-contractual fault-based civil law claim for damages caused by such systems, and (b) the burden of proof in the case of non-contractual fault-based civil law claims. Accordingly, the "AILD Proposal" does not aim at creating a new common regime of liability: since the "AILD Proposal" refers only to liability for intentional conduct or negligence for damage caused by AI systems, which continue to be subject to national substantive rules, it does not conflict, at least apparently, with the application of national substantive rules. Moreover, the "AILD Proposal" declares the character of a "minimum Directive", so that the Member States may adopt or maintain national rules that are more favourable for claimants to substantiate a non-contractual civil law claim for damages caused by an AI system, provided that such rules are compatible with European Union law [Article 1 (4)]. However, even though within the relevant limits set by Articles 3 and 4, it aims at affecting national rules in relation to which party has the burden of proof, which presumption may apply in establishing causation and/or fault, and the notion of fault. In particular, the Commission's proposal aims at improving the rights of victims who have suffered damages due to wrongful uses of AI-systems by providing specific rights on top of existing national tort-based or strict liability law, as well as the provisions of the Product Liability Directive and criminal law. Unlike the "PLD Proposal" its scope is not limited to a certain type of damage, such as damage to persons or things, but it rather covers all damages recoverable according to the corresponding national legal system, when caused by fault-based non-contractual liability. Thus, for instance, its rules would facilitate compensation also for damages caused by interference with personal rights, such as with privacy or discrimination, occurred in the course of activities that involve the use of AI-systems. Finally, the "AILD Proposal" does not conflict with the "PLD Proposal".
18. A rather different scope, although unclear at to its exact extent, has to be found under the "**Parliament AIL Proposal**" that aims at setting out common rules for the civil liability claims of natural and legal persons against operators of AI-systems in relation to any harm or damage caused by such systems to the life, health, physical integrity of a natural person, to the property of a natural or legal person, or to any significant immaterial harm resulting in a verifiable economic loss. In particular, if approved, the proposed rules would be «*without prejudice to any additional liability claims resulting from contractual relationships, as well as from regulations on product liability, consumer protection, anti-discrimination, labour and environmental protection between the operator and the natural or legal person who suffered harm or damage because of the AI-system and that may be brought against the operator under Union or national law*» [Article 2 (3)]. In terms of approximation of the national laws the approach seems to be a "minimum one", but this may only be apparent in relation to extracontractual claims against operators who are not manufacturers or similar entities. Differently from "AILD Proposal", in relation to the "high-risk AI-systems" this project suggests the adoption of a common new liability regime including rules on compensation, limitation periods and insurance.
19. The Commission's "AILD Proposal" entirely ignores the above European Parliament's Proposal. It is not clear whether this has to be construed as a total rejection by the Commission of the Parliament proposal or simply the lack of confrontation between the two institutions and their experts. What is clear is that the "AILD Proposal" has very few points, if any at all, in common with the Parliament proposal.

20. While both the "AILD Proposal" and the "Parliament AIL Proposal" refer to damages related to AI-systems only, on the contrary the "**PLD Proposal**" does not apply exclusively to violations caused by (defective) AI-systems, but to all kind of accidents caused by products and some "related services". Moreover, it follows a "maximum Directive" approach, which may generate some concerns[6]. It entails a profound review of the 85/374/EEC Directive, which it intends to replace, and although the grounds for its modification are based on the needs of circular economy and on the special characteristics of the AI-system, it is aimed to be applied to all defective products, digital or not, included in its new definition. For these reasons, the Proposal is an enormous leap forward in the protection of all victims of defective products in general .
21. Moreover, one common feature of the above proposals is that they aim at facilitating disclosure of evidence and proof of fault (or defect) and causation, these goals being necessary due to the challenges posed by emerging digital technologies in general and AI-systems in particular, namely the autonomy of some of these systems, their complexity and opacity, their open character, their interconnectivity, their vulnerability and other aspects, which may be difficult to foresee today. Nevertheless, the feasibility of implementing these proposals with the view of achieving such otherwise desirable goals is somewhat disputable, as explained below. As to the various aspects of the Commission's proposals, alternative solutions, more accurate rules and even more courageous initiatives should be taken into consideration in order to increase the protection – in terms of persons' access to the remedies provided by the law of damages – of individuals injured by products, digital services and AI-systems in the digital world.
22. Finally, it should be noted that this position paper touches on several aspects concerning artificial intelligence systems/products whilst the European Union is still working on the drafting of a uniform general legal framework concerning AI. In particular, the "**AI Act**" is still going through the ordinary legislative procedure (the Procedure 2021/0106/COD) before the EU Parliament[7]. Accordingly, even though this procedure seems to be not so far away from its end, at the time of publishing this paper (January 2024), uniform principles and rules on the development, the placing on the market, the putting into service and the use of artificial intelligence, including the legal notion itself of AI, have not been concluded yet and it is still uncertain what will be the final legislative solution in relation to many issues.

III. THE "PLD PROPOSAL".

23. As already outlined also by PEOPIL back in 2018, the Directive has not been working in the way that it was intended. In particular, in the majority of jurisdictions it has not been particularly attractive for the claimants who, where available, have opted for schemes of liability already provided by internal laws granting higher levels of protection as to the scope of manufacturers' liability and/or the burden of proof and/or limitation periods.
24. Problems for the victims highlighted by PEOPIL members mainly related to:
    - the definition of a defective product;

[6] See below § ____.

[7] On 14 June 2023 the European Parliament adopted some relevant amendments to the original proposal by the European Commission. See P9_TA(2023)0236, Artificial Intelligence Act, Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9-0146/2021 – 2021/0106(COD)). On 9th December 2023 the Council and the European Parliament reached a provisional agreement on the AI Act, which remains to be formally adopted by the European Parliament and the Council.

- the need to prove causation and the difficulties in establishing casual links, together with the tendency to reinsert a requirement for the claimants to prove fault in spite of the absence of the requirement from the Directive;
- the issue of whether or not regulatory approval provides a complete defence or is such a significant circumstance as to defeat an argument that a product is defective;
- an inability to recover damages from a supplier where the producer is known but no longer able to satisfy claims;
- the unfairness of the long stop limitation period including the unfair prejudices to those under the age of majority and to victims of products where the defect is latent and does not appear until either shortly before the end of the long stop period or afterwards;
- the widespread idea in practice that the PLD only protects "consumers" (hence, for example, the idea that a person hit by a drone while sunbathing on a beach would not be entitled to claim under the PLD).

25. Moreover:
    - producers are not subject to mandatory insurance under the "1985 PLD" so they may not have sufficient ability to address the liability of producers and distributors for damages resulting from the operation of digital and AI technologies:
    - the present 1985 Directive's scope is limited by the requirement of a "defect": even though it should be clear that such a condition is met whenever the damaging product did not provide the level of safety that the public is entitled to expect, the notion of "defect" does not seem capable of ensuring protection to the victims in all scenarios, in particular those involving digital and AI products;
    - a wide range of AI artefacts/systems may change during their lifetime due to modifications made by subjects other than the producers or by the machines themselves by way of autonomous behaviours; there may be also situations where the outcomes of the AI artefacts/systems cannot be fully determined in advance; therefore, in such cases and together with the absolute limitation period of 10 years from the date on which the producer put into circulation the actual product (see Article 11, Directive 85/374/EEC), it would be much more difficult for the victims to address their claims against the producers, this in the light of particular defences provided by the Directive 85/374/EEC to producers, who may escape from liability by proving that the product was not "defective" when put into circulation, that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered, etc.;
    - it is a widespread idea in practice that the PLD would only protect "consumers", whilst anyone can be a victim of a product (for example, a person hit by a drone while sunbathing on a beach).
26. More in general, PEOPIL, in line with the general consensus, already agreed that the application of the current Directive 85/374/EC on defective products to the digital and circular economy generates difficulties in obtaining justice to claimants and compensation for damage suffered. In particular, some of the characteristics inherent to AI-systems make it difficult to identify the potentially liable persons, to prove the product defectiveness and the causal link between the action of the potentially liable person and the damage caused. These difficulties, together with other characteristics of AI, mean that certain aspects of the current product liability regulation are insufficient or inappropriate.
27. The recent "PLD Proposal" does not seem to solve all the above pending issues in spite of the fact that some improvements are positive.

28. The Commission's draft for the new Product Liability Directive has already been attacked by the representatives of manufacturers, businesses and insurances who allege that the proposed revision may undermine Europe's competitiveness.
29. In particular, the "PLD Proposal" is under undue criticism by potential defendants on the ground that, from their point of view, it would disrupt the product liability regime set out under the "1985 PLD", which, in spite of previous criticisms, is now presented by these stakeholders as being effective and balanced between ensuring manufacturers can innovate and that consumers have fair access to compensation. The industry and insurance sides are lobbying against it by also alleging that, by pursuing a limited aim [a revision of "1985 PLD" meant to target the risks arising from the digital age around AI and Internet of Things (IoT) devices], the proposal has got to create a completely new regime that would impose on manufacturers heavy burdens in terms of the level of strict liability. Moreover, being the new directive as it is, judges and courts would be called to construe and accommodate the new rules, this with the consequence of a period of uncertainty.
30. PEOPIL have an opposite position to this way of representing the proposal: as further explained below, the proposed rules do not look revolutionary at all in relation to many profiles; for sure they shall not expose the industry to a different world in terms of civil liability. Changes were needed and one may say that the Commission's approach has been indeed too soft in facilitating victims' protection against products whose damaging features are and will become more difficult to be tackled.
31. PEOPIL also reject the argument raised by the above stakeholders that the PLD revision in the direction suggested by the Commission will produce a rise in litigation and speculative claims: in fact, higher standards for liability are such as preventing accidents taking place and limiting litigation; if litigation increases, it generally means that there are holes in the prevention. Moreover, nowadays the costs of litigation are so high that in reality they largely discourage speculative actions and it is telling that the defendants' speculation is not supported by any data. Litigation taking place on pharmaceutical products, pesticides, machines, vehicles, software, etc. proves that there is a concrete need for higher protection of persons and more effective rules on liability imposing on defendants to show full respect of safety rules and precautionary conducts besides good faith.
32. It should also be added that there is not any evidence that the Europeans' ability to compete against the backdrop of the current economic and geopolitical uncertainty depends upon the level of civil liability and compensation imposed on the industry. Apart from the circumstance that the industry itself may suffer the consequences of defective products as every day is proved, even by assuming that there is such link, PEOPIL believe that competitiveness in Europe and in the world should be encouraged by elevating the standards of protection. This should include a more victims-oriented system of liability, one that would make it inconvenient to any producer, within and outside the European Union, to introduce substandard products to the market. In the past decades we have seen the rise of out-sourced torts by Western companies that has made the global market extremely damaging in and outside Europe. Higher standards for liability are not the only instrument against this global involution, but they contribute to the development of a safer world in and outside Europe.

III.1. Level of harmonization under the PLD.

33. The level of harmonization assigned to a new liability regime by the EU legislator is always a key factor that needs careful considerations. PEOPIL's general position is that only uniform liability regimes/rules granting to injured individuals and their families the highest possible

level of protection in relation to all aspects of the right to full compensation – hence including reversal of the burden of proof, causation, access to evidence, entitlement to claim for compensation, recoverable losses, limitation periods, etc. – should benefit of a "maximum directive" approach.

34. The issue of the extent of approximation aimed at by the "PLD Proposal" is quite critical since in relation to many aspects the solutions proposed do not appear to be satisfactory irrespective of the pursued "policy of law".
35. As is well known, the Directive 85/374/EEC on liability for defective products did not aim to supersede the national rules of the law of contractual or non-contractual liability or any special liability system existing when it was notified but established harmonising rules on the basis of a so-called "maximum" Directive. This means that when Member States implemented it, they could opt for the few aspects that the Directive left to their choice, but they could not increase the level of protection that it offered.
36. Under the "PLD Proposal" the previous approach may be overturned, although, as examined below, this is far from granted.

Directive 85/374/EEC	**PLD Proposal**
Article 13	Article 2 Scope
This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.	3. This Directive shall not affect: […] (c) any rights which an injured person may have under national rules concerning contractual liability or concerning non-contractual liability on grounds other than the defectiveness of a product, including national rules implementing Union Law, such as [AI Liability Directive]; (d) any rights which an injured person may have under any special liability system that existed in national law on 30 July 1985.
	Article 3 Level of harmonisation
	Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in this Directive, including more, or less, stringent provisions to achieve a different level of consumer protection, unless otherwise provided for in this Directive.

37. These are the explanations provided by recitals (8), (9) and (10) of the "PLD Proposal":

(8) In order to create a genuine internal market with a high and uniform level of consumer protection, and to reflect the case law of the Court of Justice, Member States should not be, in respect of matters within the scope of this Directive, maintain or introduce more, or less, stringent provisions than those laid down in this Directive. (9) Under the legal systems of Member States an injured person may have a claim for damages on the basis of contractual liability or on grounds of non-contractual liability that do

not concern the defectiveness of a product, for example liability based on warranty or on fault. This includes the provisions of the [AI Liability Directive …/… of the European Parliament and of the Council], which lays down common rules on the disclosure of information and the burden of proof in the context of fault-based claims for damages caused by an AI system. Such provisions, which also serve to attain inter alia the objective of effective protection of consumers, should remain unaffected by this Directive.
(10) In certain Member States, injured persons may be entitled to make claims for damages caused by pharmaceutical products under a special national liability system, with the result that effective protection of consumers in the pharmaceutical sector is already attained. The right to make such claims should remain unaffected by this Directive.

38. By comparing Article 13 of Directive 85/374/EEC with Article 3 of the "PLD Proposal" («*Level of harmonisation*»), which has not been amended by the "12.11.2023 Parliament's PLD version", it appears that the aim of the Commission as to the extent of approximation of national laws is to introduce a significant departure from the "1985 PLD": Article 3 of "PLD Proposal" clearly and expressly provides for the rule opposite to the one characterising the "1985 PLD".
39. Nevertheless, if on one hand Article 3 of the "PLD Proposal" is unequivocal with opting for the "maximum approach", on the other hand the extent of its new rule becomes less clear either when reading its Recitals 9 and 10, or by taking into account the two clauses under Article 2 (c) and (d) that are already present in the previous model[8] and reintroduce the clarifications expressly provided by Article 13 of the current "1985 PLD". Accordingly, one may suspect that in spite of Article 3 of the "PLD Proposal" the final rule remains the previous one. Contrary to this, it is true that, differently from the previous wording of the "1985 Directive", the recital (9) of the "PLD Proposal" makes it clear that the national schemes of contractual liability and non-contractual liability that would not be prejudiced by the new product liability regime are only those that «*do not concern the defectiveness of a product, for example liability based on warranty or on fault*». However, this new version of the previous provision, inspired by the case-law of the Court of Justice[9], does not fully clarify, similarly to

[8] «*Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible*».
[9] *Commission of the European Communities v French Republic*, Judgment of the Court (Fifth Chamber) of 25 April 2002, Case C-52/00, ECLI:EU:C:2002:252, Reports of Cases 2002 I-03827, paragraphs 16 to 24: «*16.* […] *the margin of discretion available to the Member States in order to make provision for product liability is entirely determined by the Directive itself and must be inferred from its wording, purpose and structure. 17. In that connection it should be pointed out first that, as is clear from the first recital thereto, the purpose of the Directive in establishing a harmonised system of civil liability on the part of producers in respect of damage caused by defective products is to ensure undistorted competition between traders, to facilitate the free movement of goods and to avoid differences in levels of consumer protection. 18. Secondly, it is important to note that unlike, for example, Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ 1993 L 95, p. 29), the Directive contains no provision expressly authorising the Member States to adopt or to maintain more stringent provisions in matters in respect of which it makes provision, in order to secure a higher level of consumer protection. 19. Thirdly, the fact that the Directive provides for certain derogations or refers in certain cases to national law does not mean that in regard to the matters which it regulates harmonisation is not complete. 20. Although Articles 15(1)(a) and (b) and 16 of the Directive permit the Member States to depart from the rules laid down therein, the possibility of derogation applies only in regard to the matters exhaustively specified and it is narrowly defined. Moreover, it is subject inter alia to conditions as to assessment with a view to further harmonisation, to which the penultimate recital in the preamble expressly refers. An illustration of progressive harmonisation of that kind is afforded by Directive 1999/34/EC of the European Parliament and of the Council of 10 May*

the ECJ's precedents, the exact extent of such rule. As also shown by the "PLD Proposal" itself, the notion of "defectiveness" is not exempted by interactions and contaminations with the notion of "faultiness" or "dangerousness"[10], hence it is not clear yet where the margin lies. It should also be added that Recital 9, like the "1985 PLD" reference to liability for pharmaceutical products, appears to have a pure exemplary character, hence leaving open the category of cases enabling the departure from the PLD regime. Anyway, as to this last clause one may ask whether it does make sense that the rule-exception in question should be limited to pharmaceutical products only, as the need for an equal protection of injured persons may arise in relation to other products similar - in terms of difficulties in assessing liability - to such artefacts, like, for example, medical devices, chemical products, food, mobile phones, etc.

40. On the basis of the above considerations, it is possible to conclude that the "PLD Proposal" provisions and recitals on the level of harmonisation do not bring any particular added value in terms of clarification of the exact extent of the approximation of national laws aimed at by the EU law: the uncertainties in this regard also evidenced and not fully solved by the case-law of the European Court of Justice[11] remain mostly intact under the "PLD Proposal".
41. A clever proposal for solving these uncertainties has been put forward by the European Law Institute (ELI), a private non-profit organisation, in its "*ELI Draft of a Revised Product Liability Directive*" published in 2022[12], hereinafter the "ELI PLD Proposal".
42. Nevertheless, this proposal, which goes beyond the (still unclear) level set by the above case-law of the Court of Justice and the "PLD Proposal" itself, adheres to the "Maximum Directive" approach which is opposite to the position supported by PEOPIL in this position

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1999 amending Council Directive 85/374/EEC (OJ 1999 L 141, p. 20), which by bringing agricultural products within the scope of the Directive removes the option afforded by Article 15(1)(a) thereof. 21. In those circumstances Article 13 of the Directive cannot be interpreted as giving the Member States the possibility of maintaining a general system of product liability different from that provided for in the Directive. 22. The reference in Article 13 of the Directive to the rights which an injured person may rely on under the rules of the law of contractual or non-contractual liability must be interpreted as meaning that the system of rules put in place by the Directive, which in Article 4 enables the victim to seek compensation where he proves damage, the defect in the product and the causal link between that defect and the damage, does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect of latent defects. 23. Likewise the reference in Article 13 to the rights which an injured person may rely on under a special liability system existing at the time when the Directive was notified must be construed, as is clear from the third clause of the 13th recital thereto, as referring to a specific scheme limited to a given sector of production. 24. It follows that […] *the Directive seeks to achieve, in the matters regulated by it, complete harmonisation of the laws, regulations and administrative provisions of the Member States* […]». Same interpretation was rendered by the Court of Justice on the same date in *Commission of the European Communities v Hellenic Republic*, Judgment of the Court (Fifth Chamber) of 25 April 2002, Case C-154/00, ECLI:EU:C:2002:254, Reports of Cases 2002 I-03879, paragraphs 10 to 20, and *María Victoria González Sánchez v Medicina Asturiana SA*, Judgment of the Court (Fifth Chamber) of 25 April 2002, Case C-183/00, ECLI:EU:C:2002:255, Reports of Cases 2002 I-03901, paragraphs 23 to 32.

[10] This concept, for example, is central under Article 2050 of the Italian Civil Code: «*Whoever causes injury to another in the performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable for the damage, unless he or she proves that he or she has adopted all suitable measures to avoid the injury*». Under Italian case-law the established trend is to apply this article to damages caused by products like pharmaceutical products instead of the PLD.

[11] See previous footnote.

[12] Available at *www.europeanlawinstitute.eu*. In particular, see Article 4 («*Level of Harmonisation*»): «*1. Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in this Directive, including more or less stringent provisions to ensure a different level of compensation for victims, unless otherwise provided for in this Directive. 2. Unless a matter has been addressed by this Directive, Member States are free to apply their general rules and principles of non-contractual liability to liability under this Directive, or any special rules and principles. 3. This Directive shall not affect any rights which a victim may have according to law that remain unaffected by this Directive according to Article 2(3)*».

paper for the reasons already above outlined. In particular, should the level of protection granted by the future revision of the "1985 PLD" remain the same as the one set by the Commission in its "PLD Proposal", then the approach to harmonisation should be kept at minimal terms according to the "1985 PLD" model.

III.2. __The new notion of "product"__.

43. One may object against the captivating sentence that «*every product can become a 'smart' product*»[13], but it is clear that not only most of the traditional products will be affected - when conceived, made and in the course of their life - by new technologies (including AI systems), but many products, digital services and AI artefacts/systems will become one single thing in the digital world.
44. The 1985 Directive was conceived having in mind products that were tangible and, so to say, "analogical". Accordingly, there is no doubt that there are many aspects that should be amended to enable the application of the existing EU producers' liability regime to new technologies and AI-systems, more in general to the products of the so-called "digital age".
45. According to such a need, the "PLD Proposal" provides for a new broader definition of "product".

Directive 85/374/EEC	**PLD Proposal**
Article 2	Article 4 Definitions
For the purpose of this Directive, 'product' means all movables even if incorporated into another movable or into an immovable. 'Product' includes electricity.	For the purpose of this Directive, the following definitions shall apply: (1) 'product' means all movables, even if integrated into another movable or into an immovable. 'Product' includes electricity, digital manufacturing files and software; (2) 'digital manufacturing file' means a digital version or a digital template of a movable; (3) 'component' means any item, whether tangible or intangible, or any related service, that is integrated into, or inter-connected with, a product by the manufacturer of that product or within that manufacturer's control; (4) 'related service' means a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions; (5) 'manufacturer's control' means that the manufacturer of a product authorises a) the integration, inter-connection or supply by a third party of a component including software updates or upgrades, or b) the modification of the product; […]

[13] S. LOHSSE, R. SCHULZE, D. STAUDENMAYER, *Liability for Artificial Intelligence*, in *Liability for Artificial Intelligence and the Internet of Things*, S. LOHSSE, R. SCHULZE, D. STAUDENMAYER (EDS.), 1st ed., Baden-Baden, 2019, 11.

	(7) ‘data’ means data as defined in Article 2, point (1), of Regulation (EU) 2022/868 of the European Parliament and of the Council; (17) ‘online platform’ means online platform as defined in Article 2, point (h), of Regulation (EU)…/… of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act).

46. These are the explanations provided by recitals of the “PLD Proposal”:

(12) Products in the digital age can be tangible or intangible. Software, such as operating systems, firmware, computer programs, applications or AI systems, is increasingly common on the market and plays an increasingly important role for product safety. Software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component, and is capable of causing damage through its execution. In the interest of legal certainty it should therefore be clarified that software is a product for the purposes of applying no-fault liability, irrespective of the mode of its supply or usage, and therefore irrespective of whether the software is stored on a device or accessed through cloud technologies. The source code of software, however, is not to be considered as a product for the purposes of this Directive as this is pure information. The developer or producer of software, including AI system providers within the meaning of [Regulation (EU) …/… (AI Act)], should be treated as a manufacturer. (13) In order not to hamper innovation or research, this Directive should not apply to free and open-source software developed or supplied outside the course of a commercial activity. This is in particular the case for software, including its source code and modified versions, that is openly shared and freely accessible, usable, modifiable and redistributable. However where software is supplied in exchange for a price or personal data is used other than exclusively for improving the security, compatibility or interoperability of the software, and is therefore supplied in the course of a commercial activity, the Directive should apply. (14) Digital manufacturing files, which contain the functional information necessary to produce a tangible item by enabling the automated control of machinery or tools, such as drills, lathes, mills and 3D printers, should be considered as products, in order to ensure consumer protection in cases where such files are defective. For the avoidance of doubt, it should also be clarified that electricity is a product. (15) It is becoming increasingly common for digital services to be integrated in or interconnected with a product in such a way that the absence of the service would prevent the product from performing one of its functions, for example the continuous supply of traffic data in a navigation system. While this Directive should not apply to services as such, it is necessary to extend no-fault liability to such digital services as they determine the safety of the product just as much as physical or digital components. Such related services should be considered as components of the product to which they are inter-connected, when they are within the control of the manufacturer of that product, in the sense that they are supplied by the manufacturer itself or that the manufacturer recommends them or otherwise influences their supply by a third party.

47. Article 2 of the Directive 85/374/EC operates with the traditional notion of "product" limited to all movables, including those which have been incorporated into an immovable, and to electricity. Under the "1985 PLD" there are doubts on whether software, under certain circumstances, qualifies as a "product" or not for the purposes of the directive. Services are not included in the definition of product within the "old" scheme.
48. The limited scope of the 1985 notion together with the digital revolution and the developments of new categories of products and services have clearly rendered Directive 85/374/EC outdated firstly in relation to the notion of "product" itself. One example may be sufficient to show the new dimension of the notion of "product" we are dealing with. The current reality includes Generative artificial intelligence (genAI) systems that are capable of generating text, images, or other media in response to prompts; these AI models acquire the patterns and structure of their input training data by applying neural network machine learning techniques, and then generate new data that has similar characteristics. Clearly, this puts everybody before a completely different world when approaching the issue of "products".
49. Accordingly, PEOPIL welcome the new dimension of the category of "product" offered by the "PLD Proposal" as also confirmed by the "12.11.2023 Parliament's PLD version". Nevertheless, as alleged in the paragraphs below, the new rules should be amended and improved by way of either modifications to the texts of the proposed articles or, where it may be held sufficient, via the introduction of additional and/or revised recitals. We believe that there is still a lot of work to be done in relation to the new dimension of "products" under the revision of the 1985 Directive.
50. First of all, PEOPIL see as being positive the explicit inclusion of software and new scenarios of products' dimensions within the scope of the proposal. In particular, the "PLD Proposal", in order to avoid any doubts, not only continues to mention electricity in the definition of "product", but it also adds to it "digital manufacturing files and software" [Article 4 (1) "PLD Proposal"] and what it calls "related services" [Article 4 (4) "PLD Proposal"].
51. The inclusion of software, conveniently defined by the proposal in very broad terms as including such «*operating systems, firmware, computer programs, applications or AI systems*» [see Recital 12], is to be welcomed, since software plays an important role in product safety in general as well as in relation to AI-systems and new technologies, even though one may object that the reference to AI as "software" is not entirely correct.
52. The explicit reference by the future PLD to "software" is necessary for the sake of both consumer protection and legal certainty, regardless, as also put by the "PLD Proposal", of how it is supplied or used and, therefore, regardless of whether the software is stored on a device or accessed through cloud technologies. Nevertheless, the "PLD Proposal" may be challenged where at Article 4 it does not define the scope of the category "software" and leaves all matters concerning it to the recitals.
53. Moreover, given the increasing importance of AI systems and the risks that are being associated with such systems we believe that reference to AI systems should also be found within the body of the future PLD (in particular, Article 4) by adding it to the list provided by Article 4 (1) point 1 in relation to the notion of "product" and by adding a definition of "AI systems".
54. In particular, Article 4 (1) 1, as amended by the "12.11.2023 Parliament's PLD version", should be further modified in this way: « *'product' means all movables, even if integrated into or inter-connected with another movable or into an immovable. 'Product' includes*

*electricity, digital manufacturing files, raw materials****,*** *software,* ***AI systems and online platforms****»*[14].

55. As to the definition of "AI systems" there should be one single definition within the EU law. More specifically, the definition to be adopted by the future PLD should be coherent with the AI Act. Consequently, the new PLD at Article 4 should make explicit reference to the notion provided by the AI Act (not approved yet on January 2024), this being the same approach correctly followed by the "AILD Proposal"[15].
56. The industry has shown some reluctance against the inclusion of software within the new strict liability regime as it would raise some questions in relation to the concept of defectiveness and would impose greater legal exposure on software and other similar new technologies developers. The industry's fears in relation to such update of the old directive are not surprising indeed in an age where a vast majority of the products consist of or depend on software. PEOPIL agree that it is not an easy task to accommodate the notion/requirement of defectiveness to such "products"; however, this does not prove that the liability for software should be taken out of the new directive, nor that the requirement of defectiveness should be somehow made more stringent. In fact, in the digital age it would not make sense not to consider software as a product and include it under the same regime of traditional products. Instead, this inclusion should impose that whenever the product that allegedly caused the damage involved in its functioning a software or consisted of a software the Proposal should introduce further elements that facilitate, even more than in other cases, the reversal of the burden of proof on producers/developers.
57. PEOPIL also welcome the idea that the liability regime under the directive should not apply to free and open-source software (FOSS), or free/libre and open-source software (FLOSS); nevertheless, that this exemption is linked to the requirement that it should apply in relation to software "developed or supplied outside the course of a commercial activity" may be extremely inaccurate and may generate some level of uncertainty.
58. By contrast, PEOPIL consider that the reference to "digital manufacturing files" - i.e. digital version or digital template of a movable [Article 4(2) of the "PLD Proposal") which contains the functional information necessary to produce a tangible item (for instance with 3D printer) - is unnecessary, since it can already be included alternatively under the notion of "software" or the category of "digital content". Anyway, PEOPIL fully agree that "digital manufacturing files" should fall under the notion of "product".
59. Article 4 or Recital 12 should be amended in order to include combinations of both software and hardware and their components, whether tangible or intangible, including all mathematical framework, clouds, digital storages and applications irrespective of whether purchased by way of a download or as a "software-as-a-service" ("SaaS"), i.e. applications run in a cloud and subscribed for by the users without being purchased, with access ensured over the Internet, whether supplied for professional or private use, for payment or, under some conditions, free of charge.
60. The new PLD should similarly clarify that "software" also includes models, algorithms and other mathematical framework employed specifically for the purpose of producing outputs available for use by consumers. This is to avoid defensive strategies possibly adopted by the creators of the so-called "foundation models" (such as GPT4), who often claim that such models "are more accurately described as a combination of software and pre-trained machine learning models, which are more than just traditional software", "they are a fusion of software

[14] As to online platforms see below in this paragraph.
[15] On this approach and the definition of AI systems see paragraph ____ below.

engineering and machine learning, leveraging the power of large-scale data and deep neural networks to perform complex language-related tasks", etc. Their argument ultimately boils down to the claim that certain abstract mathematical "constructs" (nodes or artificial neurons) are implemented using special algorithms and run on special-purpose computing hardware. Accordingly, the risk that needs to be limited as much as possible is that it may become easy to escape from the category of "product" on the grounds that neither the hardware nor the software, left without the mathematical formulas ("constructs"), are capable of producing any outputs/influence on consumers.

61. Furthermore, the proposal is not entirely clear as to whether "SaaS", bought on the basis of a subscription model and different from the software purchased as a standalone application subject to periodical updating, is also a "product" for the purposes of the meaning of Article 4 (1) of the "PLD Proposal". Although the inclusion of "SaaS" should be granted by Article 4 (4) where it extends the scope of the notion of "product" to "related digital services", PEOPIL believe that the provision should make it clear that "SaaS" is also comprised. Parts of the "SaaS" initially remaining on a cloud should be treated in the same way of software packages' components available as downloads.
62. As to clouds, digital storages and "SaaS" one may also object that such items are included within the new notion of "product" where the "PLD Proposal" [Article 4 (17)] includes, as it should be, "online platform" as now defined by Article 3 (i) of the Regulation (EU) 2022/2065 of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act)[16]. As already anticipated above[17], for the sake of clarity we suggest that "online platform" should also be expressly listed by Article 4 (1) point 1, given the importance and risks associated to these digital products.
63. Unfortunately, the list under Recital 12 does not specify whether it also includes other digital products that do not qualify as "software", like, for example, a "digital content" as defined by the Directive (EU) 2019/770 of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services (the so-called "Digital Content Directive")[18]. Logically, this should not be an issue in relation to "data" as pure information supplied in the digital form: there should not be any doubt that the mere information relating to a person, a thing or any event falls outside the said list. However, there may be "digital contents" other than pure information that may become functionally comparable to software as a product in spite of the possible lack of autonomy in performing specific tasks. Such digital contents may fall under the list provided by Recital 12 which, by the way, shows an exemplary function only and anyhow should be construed as having such nature.
64. The exclusion from the scope of the Directive of free and open-source software, unless it is supplied in exchange for a price or personal data, which is not used exclusively to improve the security, compatibility or interoperability of the software and are therefore supplied in the course of a commercial activity, also seems appropriate and reasonable. Although it can be contended that these exceptions can be inferred from the other rules contained in the Directive (for instance, the link between "product" and an action "in the course of commercial activity" [cf. Article 4 (9), 4 (10) and 4 (14) "PLD Proposal", in the case of free and open-source

[16] In particular: «*'online platform' means a hosting service that, at the request of a recipient of the service, stores and disseminates information to the public, unless that activity is a minor and purely ancillary feature of another service or a minor functionality of the principal service and, for objective and technical reasons, cannot be used without that other service, and the integration of the feature or functionality into the other service is not a means to circumvent the applicability of this Regulation*».
[17] See point ___ above.
[18] See Article 2(1): «*'digital content' means data which are produced and supplied in digital form*».

software], it seems that they should be included in the definition of a product in Article 4 (1) PLD to clarify the binding effect of these exceptions.

65. PEOPIL welcome the extension of the notion of product to “related services” too [Article 4(4) “PLD Proposal”), since digital services are integrated or interconnected with most of new technologies in such a way that the absence of the service would prevent these products from performing some, if not all, of their functions. It is necessary to extend the liability regime to such services. It is not clear whether “related services” referred to by the “PLD Proposal” are restricted to the ones falling under the notion of “digital service” provided by Article 2(2) of Directive (EU) 2019/770, where «*‘digital service’ means: (a) a service that allows the consumer to create, process, store or access data in digital form; or (b) a service that allows the sharing of or any other interaction with data in digital form uploaded or created by the consumer or other users of that service*».
66. As to the definition of “component” [Article 4(3) of the “PLD Proposal”) PEOPIL suggests that the proposed provision should be integrated by clarifying that the concerned item may fall within this notion “whether raw or not”. Moreover, it should make it clear that the notion also includes any “digital element” that may be incorporated into or coupled with the product, as defined by the Digital Content Directive 2019/770.
67. Finally, the need for reviewing the “1985 PLD” arising from the digital revolution and the new technologies should not lead to overshadowing that since 1985 the list of products and “emerging risks” belonging to the “real world” and affecting individuals’ health has expanded significantly and is likely to increase in near future. Asbestos, vaccines, pesticides, opioids, chemicals, electromagnetic waves emanated by various artefacts are some examples of the litigation that has arisen since the enactment of the present PLD. It should also be considered that in the past forty years we have also seen the development of products like the ones based on/combined with human body parts, such as blood, cells, or tissue, on/with animals’ parts, as well as on/with waste. As to such products the new directive should make it clear that such products fall within the notion of “product”.

III.3. Scope of protection: the incomplete list of liable persons and potential defendants under the “PLD Proposal”.

POTENTIAL DEFENDANTS	
Directive 85/374/EEC	**PLD Proposal**
Article 3	Article 7 Economic operators liable for defective products
1. ‘Producer’ means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer. 2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer	1. Member States shall ensure that the manufacturer of a defective product can be held liable for damage caused by that product. Member States shall ensure that, where a defective component has caused the product to be defective, the manufacturer of a defective component can also be held liable for the same damage. 2. Member States shall ensure that, where the manufacturer of the defective product is

within the meaning of this Directive and shall be responsible as a producer. 3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.	established outside the Union, the importer of the defective product and the authorised representative of the manufacturer can be held liable for damage caused by that product. 3. Member States shall ensure that, where the manufacturer of the defective product is established outside the Union and neither of the economic operators referred to in paragraph 2 is established in the Union, the fulfilment service provider can be held liable for damage caused by the defective product. 4. Any natural or legal person that modifies a product that has already been placed on the market or put into service shall be considered a manufacturer of the product for the purposes of paragraph 1, where the modification is considered substantial under relevant Union or national rules on product safety and is undertaken outside the original manufacturer's control. 5. Member States shall ensure that where a manufacturer under paragraph 1 cannot be identified or, where the manufacturer is established outside the Union, an economic operator under paragraph 2 or 3 cannot be identified, each distributor of the product can be held liable where: (a) the claimant requests that distributor to identify the economic operator or the person who supplied the distributor with the product; and (b) the distributor fails to identify the economic operator or the person who supplied the distributor with the product within 1 month of receiving the request. 6. Paragraph 5 shall also apply to any provider of an online platform that allows consumers to conclude distance contracts with traders and that is not a manufacturer, importer or distributor , provided that the conditions of Article 6(3) set out in Regulation (EU)…/… of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act) are fulfilled.

III.3.1. The potential defendants under the "PLD Proposal".

68. The "PLD Proposal" appears to significantly expand the list of potential defendants. In particular, the Proposal adds some new actors/defendants and introduces the supra concept of "economic operator" to encompass all persons who may end up being liable under the rules it lays down. One of these "economic operators" is the manufacturer, which includes the manufacturer in the strict sense, with some new nuances, and the own-brander. Of course, these were within the definition of producers within the 1985 PLD. Additionally, the concept of "economic operator" includes, in addition to the manufacturer of a product or component, the "provider of a related service", the "authorised representative", the "importer", the "fulfilment service provider" and the "distributor", plus, according to Article 7 (6), the "provider of an online platform".
69. The Proposal associates to this list of "economic operators" a cascade-like liability model which is more complex and adequate to modern-digital supply chains than the 1985 model, but leads to the same conclusion: it provides for the backup liability of the distributor if none of the other "economic operators" in the list are identified.
70. PEOPIL find both the list and the cascade largely positive.
71. Nevertheless, the "PLD Proposal" should be amended in order to consider the following points.
72. First of all, there is not any reason why the "provider of an online platform" should be relegated to the bottom of the cascade, at least unless they act as mere providers hence without any role typical of manufacturers or distributors: in fact, providers of such platforms are better placed to identify the importer or the representative, than the fulfilment service providers.
73. Secondly, the assessment of liability in the case of "modifications" seems to be complicated rather than facilitated by the "PLD Proposal". This topic is relevant since, at least in general, modifications significantly increase the risk of damaging events. Besides this, individuals' freedom to opt for updates/upgrades is extremely limited in practice: without such modifications there are products that would become obsolete and/or not functional to the assigned goals/tasks. The "PLD Proposal" addresses these issues on the ground of the category of "substantial modification". In particular, Article (7) 4 refers to the notion of "substantial modification" by stating that this modification is the one considered to be substantial under relevant Union or national rules on product safety and is undertaken outside the original manufacturer's control. Recital 29 of the "PLD Proposal" does not add too much to clarify this definition apart from stating that «*Whether a modification is substantial is determined according to criteria set out in relevant Union and national safety legislation, such as modifications that change the original intended functions or affect the product's compliance with applicable safety requirements*». These last indications seem to largely reflect Article 3 (31) of the *Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020* [2022/0272 (COD)] which provides for the following definition: «*'substantial modification' means a change to the product with digital elements following its placing on the market, which affects the compliance of the product with digital elements with the essential requirements set out in Section 1 of Annex I or results in a modification to the intended use for which the product with digital elements has been assessed*». Having described this framework, the concept of "substantial modification" may create serious problems as to the assessment of liabilities, this with particular reference to digital/AI products. In fact, the "substantial modification" may occur while the product is no longer under the control of the original manufacturer. However, there are cases where this manufacturer accepted the risks connected with alterations and paved the way to substantial

modifications, making them an essential part of the business. In such cases the original manufacturer should not be exempted from liability under the PLD. To this respect it is positive that the "12.11.2023 Parliament's PLD version" has proposed to amend the notion of "manufacturer's control" by adding that this control occurs whenever «*the manufacturer of a product performs or, with respect to the actions of a third party, explicitly authorises or consents to a) the integration, inter-connection or supply by a third party of a component including the specific software updates or upgrades, or b) the modification of the product, including substantial modifications*». Nevertheless, this expansion of the notion is restricted to the explicit authorization or consent to substantial modifications, whilst the mere acceptance, as part of the commercial strategies, of this possibility would not be sanctionable. Moreover, reference to the "manufacture's intended use" may not encompass all potential uses/misuses of the product. Accordingly, PEOPIL suggest that reference should be made to any "potential use/misuse" which was reasonably foreseeable by the manufacturer at the time the product was put into circulation or modified by the same manufacturer.

74. We disagree with Recital 29 where it states that «*Economic operators that carry out repairs or other operations that do not involve substantial modifications should not be subject to liability under this Directive*». There can be cases where such operators realize or could have realized the defect but they do not do anything, including informing the owner or the user of the product.
75. As to Article 7 (5), there is not any reason why the liability of distributors should be limited to the case of non-disclosure. There can be cases where the distributors have actually contributed to the chain of events with acts and/or omissions, for example by not undertaking all due initiatives in relation to the recall campaign of a defective product[19]. Identifying the manufacturer should not be a defence to the distributor when the manufacturer cannot meet the claims[20].
76. At the top, under the "PLD Proposal" it should made clear that all "economic operators" remain liable and exposed to the claimants' actions irrespective of whether there are potential defendants in the preceding or following levels of the cascade.
77. It should also be noted that in its ***Opinion 42/2023 on the Proposals for two Directives on AI liability rules***, dated 11th October 2023, the European Data Protections Supervisor (EDPS) observed that «*neither the AILD Proposal, nor the PLD Proposal would appear to apply in cases of damages stemming from AI systems produced and/or used by EU institutions, bodies*

[19] For instance, under the EU Regulation 745/17 on Medical Devices the notion of distributors is broad, they share important tasks with other "economical operators"; sometimes subsidiaries of the manufacturer are distributors, too.

[20] The PIP breast implant scandal revealed large gaps in consumer protection and remedy. PIP was a French company who manufactured silicon breast implants. In 2010 the French licensing authorities went into their factory and discovered a wholesale fraud being committed in the manufacturing of the implants to avoid having to follow the expense of that required by the CE marking. They used non-medical grade silicon and later removed one of the protective shells. This became the subject of a worldwide medical device alert. These implants were sold throughout Europe, South America and Australia. The owners of the company admitted to fraud and were imprisoned. Their public liability insurers declined to indemnify them although were eventually made to provide a limited indemnity to French nationals only. The Product Liability Directive and its incorporation in EU states did not provide any remedy as the manufacturer was without adequate means or indemnity to satisfy claims and the suppliers avoided liability by being able to disclose the manufacturer. UK nationals were able to use domestic statutes (Sale of Goods Act 1979 and Supply of Goods and Services Act) 1973 implied a strict condition of satisfactory quality and fitness for purpose into contracts) to recover damages on behalf of victims against those who sold the implant to whether it be surgeons or clinics. However, victims in the rest of the EU and internationally did not have this remedy. Some have had to bring claims against the notifying body in the French courts; this has been a slow and arduous process which is still going now. The suppliers had enjoyed significant income and profit from selling these implants: it was wrong that they should have been able to enjoy an immunity from damages claims. As drafted this revised directive would not provide a remedy for these victims.

and agencies» (point 12). Consequently, EDPS suggested that the new rules should ensure that individuals who have suffered damage caused by AI systems produced and/or used by EU institutions, bodies and agencies are not placed in less favourable position and can enjoy an equivalent level of protection as provided for in the "PLD Proposal" as well as in the "AILD Proposal"[21]. We agree with this suggestion which at least should be incorporated into a specific recital of the new directives.

78. Finally, the potential defendants' list/cascade provided by the "PLD Proposal" do not consider and address the role/liability of EU and national authorities responsible for managing the surveillance of the safety of products/services, as well as of notified bodies, auditors, certification entities, conformity assessment bodies, surveyors, etc. This lack of consideration occurs in spite of the fact that all these subjects are becoming more and more important not only in granting that products are safe, but also in contributing to the products' safeness itself. Moreover, it should be taken into consideration that there are products and services entering into the European Union's market only because they are certified as safe and quality-checked. The importance of such public and private entities is also confirmed by the text of the Artificial Intelligence Act adopted by the European Parliament on 14 June 2023 as well as by the original proposal laid down by the European Commission, whereby authorities at the EU and national levels, notified bodies and "conformity assessment bodies" are called to play a relevant part in guarantying the quality of the AI systems.
79. Having said this, PEOPIL is aware that the inclusion of the liability of these subjects under the future revised PLD would give rise to a complex debate and several intricate questions, hence it may jeopardise the approval of the new PLD whose adoption is imposed by the ongoing digital revolution as a matter of urgency. Accordingly, at this stage PEOPIL agree that the area of liability related to the above entities should not be addressed by the new directive. Nevertheless, even though in some Member States it is already possible to sue these entities as defendants for their negligent conducts and omissions, we stress the need for national laws and a future EU legislative initiative to establish a uniform cause of action addressing the liability of such bodies, irrespective of their public or private nature, besides the liability of the manufacturers and the other "economic operators", at least whenever the producer no longer exists or has no adequate insurance or liability of the other defendants is capped. Under this future scheme claimants should be entitled to sue these defendants separately as well as jointly with the other "economic operators" listed by the "PLD Proposal". Moreover, PEOPIL believe that in relation to criminal or civil court proceedings brought in any of the Member States of the European Union against these subjects any form of jurisdictional immunity should be clearly banned by the Member States and the European Union, this, in particular, whenever a fundamental right granted by the Charter of the Fundamental Rights of the European Union or by the European Convention on Human Rights and Fundamental Freedoms has been infringed. The inclusion of a recital within the future PLD expressing all above considerations would be extremely positive towards higher safety standards.

III.3.2. The lack of coordination among the "PLD Proposal" and the "AILD Proposal".

[21] Point 14 of the Opinion: «*Mindful of the different legal frameworks for non-contractual liability applicable to Member States and to EUIs, the EDPS calls upon the co-legislators and the Commission to consider the necessary measures to address this situation, and thus ensure that individuals who have suffered damages caused by AI systems produced and/or used by EU institutions, bodies and agencies are not placed in a less favourable position and enjoy the same standards of protection as individuals who suffered damages caused by AI systems produced and/or used by private actors or national authorities*».

80. It should also be noted that there has not been any particular attempt to adequately coordinate the future PLD with the proposed AILD, even if the former should play a fundamental role in relation to artificial intelligence systems too. The "12.11.2023 Parliament's PLD version" even deleted any reference by Recital 9 to the "AILD Proposal" when mentioning other rules providing for liability.

III.4. Scope of protection: the potential claimants, the notion of "damage" and the protected rights (right to health and physical/psychiatric integrity; the protection of the moral/emotional/psychological sphere; rights of personality; property; data).

POTENTIAL CLAIMANTS	
Directive 85/374/EEC	**PLD Proposal**
(see Article 9)	Article 5 Right to compensation
-	1. Member States shall ensure that any natural person who suffers damage caused by a defective product ('the injured person') is entitled to compensation in accordance with the provisions set out in this Directive. 2. Member States shall ensure that claims for compensation pursuant to paragraph 1 may also be brought by: (a) a person that succeeded, or was subrogated, to the right of the injured person by virtue of law or contract; or (b) a person acting on behalf of one or more injured persons in accordance with Union or national law.

DAMAGES AND PROTECTED RIGHTS	
Directive 85/374/EEC	**PLD Proposal**
Article 9	Article 4 Definitions
For the purpose of Article 1, 'damage' means: (a) damage caused by death or by personal injuries; (b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property: (i) is of a type ordinarily intended for private use or consumption, and (ii) was used by the injured person mainly for his own private use or consumption. This Article shall be without prejudice to national provisions relating to non-material damage.	(6) 'damage' means material losses resulting from: (a) death or personal injury, including medically recognised harm to psychological health; (b) harm to, or destruction of, any property, except: (i) the defective product itself; (ii) a product damaged by a defective component of that product; (iii) property used exclusively for professional purposes; (c) loss or corruption of data that is not used exclusively for professional purposes;
Explanations	Explanations

Whereas the protection of the consumer requires compensation for death and personal injury as well as compensation for damage to property; whereas the latter should nevertheless be limited to goods for private use or consumption and be subject to a deduction of a lower threshold of a fixed amount in order to avoid litigation in an excessive number of cases; whereas this Directive should not prejudice compensation for pain and suffering and other non-material damages payable, where appropriate, under the law applicable to the case;	(16) In recognition of the growing relevance and value of intangible assets, the loss or corruption of data, such as content deleted from a hard drive, should also be compensated, including the cost of recovering or restoring the data. As a result, the protection of consumers requires compensation for material losses resulting not only from death or personal injury, such as funeral or medical expenses or lost income, and from damage to property, but also for loss or corruption of data. Nevertheless, compensation for infringements of Regulation (EU) 2016/679 of the European Parliament and of the Council41, Directive 2002/58/EC of the European Parliament and of the Council42, Directive (EU) 2016/680 of the European Parliament and of the Council43 and Regulation (EU) 2018/1725 of the European Parliament and of the Council44 is not affected by this Directive. (17) In the interests of legal certainty, it should be clarified that personal injury includes medically recognised damage to psychological health. (18) While Member States should provide full and proper compensation for all material losses resulting from death, or personal injury, or damage to or destruction of property and data loss or corruption, rules on calculating compensation should be laid down by Member States. Furthermore, this Directive should not affect national rules relating to non-material damage. (19) In order to protect consumers, damage to any property owned by a natural person should be compensated. Since property is increasingly used for both private and professional purposes, it is appropriate to provide for the compensation of damage to such mixed-use property. In light of this Directive's aim to protect consumers, property used exclusively for professional purposes should be excluded from its scope.

DAMAGES AND PROTECTED RIGHTS	
PLD Proposal	**12.11.2023 Parliament's PLD version**
Article 4 Definitions	Article 5a Damage

(6) ‘damage’ means material losses resulting from: (a) death or personal injury, including medically recognised harm to psychological health; (b) harm to, or destruction of, any property, except: (i) the defective product itself; (ii) a product damaged by a defective component of that product; (iii) property used exclusively for professional purposes; (c) loss or corruption of data that is not used exclusively for professional purposes;	1. For the purpose of this Directive, ‘damage’ means material losses resulting from: (a) death or personal injury, including medically recognised damage to psychological health; (b) damage to, or destruction of, any property, except: (i) the defective product itself; (ii) a product damaged by a defective component of that product that is integrated into, or inter-connected with, a product by the manufacturer of that product within that manufacturer’s control; (iii) property used exclusively for professional purposes; (c) destruction or irreversible corruption of data that are not used for professional purposes, provided that the material loss exceeds EUR 1000. 2. This Article shall not affect national rules relating to non-material damage as well as those relating to the compensation of damage under other liability regimes.

III.4.1. The restricted category of potential claimants.

81. Under the new Recital 16 as drafted by both versions of the “PLD Proposal” (the original one by the Commission and the “12.11.2023 Parliament’s PLD version”) reference is still made, as it is under the 1985 PLD, to «*the protection of consumers*», an expression which limits the scope of the PLD to “consumers” only. This reference can also be found in other recitals of the proposals. We believe that reference to “consumer” is too limiting since there are primary victims who may not qualify as “consumers” from a strict contractual perspective; there are also “secondary victims” as well as bystanders who may be entitled to seeking compensation for damages without technically qualifying as “consumers”. Accordingly, it is positive that the rules suggested by the above pending proposals do not limit the category of claimants to “pure (contractual) consumers”, hence there should not be any issue in the future in relation to the scope of this category which is confirmed to apply to any “natural person” damaged by a defective product according to the list of infringements provided by Article 4 (Commission’s version) and Article 5a (“12.11.2023 Parliament’s PLD version”).
82. Nevertheless, since in practice - even among the judiciary - there is some confusion as to the category of claimants allowed to claim compensation on the ground of the PLD, it would be necessary to completely banish the ungrounded idea that the PLD protects “consumers” only whilst anyone, irrespective of this qualification, can be a victim of a defective product (for example, a person hit by a drone while sunbathing on a beach). Accordingly, PEOPIL suggest that the new PLD should establish an express reference to the fact that all individuals – including persons who fall outside any contractual relationship with the economic operators indicated by the directive like for example also bystanders - are protected by the directive. Alternatively, under Recital 16 reference should be made to the “protection to individuals” instead of the “protection of consumers”.

83. Moreover, Article 5 of the "PLD Proposal", which follows Article 1 («*Subject matter*»)[22] and remains as such under the "12.11.2023 Parliament's PLD version", makes it clear that the scope of potential claimants is restricted to "natural persons" only, this being in line with the approach followed in 1985 and the revised notion of "damage".
84. PEOPIL suggest that this restriction should be reviewed for at least two reasons:
    - there are legal persons that, from the perspective of damage suffering, are equal to natural persons (for example, when the injured person suffering a bodily injury is the owner and manager of a small company centred around him/her, this company should be entitled to claim for the loss of profits; in some Member States it is the company itself and not the injured person which is entitled to claim for such loss; family companies established for the management of properties or funds are another example. Moreover, one should consider the employer's claim for the pecuniary losses arising from the injury sustained by an employee due to a defective product used in the course of the employment; finally, under some jurisdictions heirs of killed or injured persons are not entitled to claim separately, but by means of a legal entity, the "estate", that would be prevented from suing under Article 5 of the "PLD Proposal");
    - legal persons are not all equal in relation to the knowledge and management of the risks associated to products, this being even truer in the digital/IA world where the gap between the developers of new technologies and a vast category of companies purchasing such products, even though for "professional purposes", is enormous: there are companies that are not in a position different from the consumers' one;
    - the category of legal persons may also include associations and other similar entities that are relevant for class actions and collective representative actions.
85. As noted below[23], the restriction of the category of claimants to natural persons only is in contrast with the different approach followed by the European Commission in the "AILD Proposal" that at Article 2 (6) and (7) («*Definitions*») expands the notion of 'claimant' to both natural and legal persons. That legal persons can rely on special rules on liability whenever they sue operators and users but are excluded from any facilitating rule when they sue the producers has not got any reasonable explanation. This different treatment does not make any sense at all, in particular by considering that the two proposals here under scrutiny belong to the same "package".
86. Accordingly, PEOPIL suggest that the reference to natural persons should be deleted from both Articles 1 and 5 of the "PLD Proposal". Moreover, the reference to "professional purposes" should also be limited to the cases where manufacturers and buyers are equal, this not being the case of an engineer, a lawyer or a doctor running their own firms alone or together with some colleagues.

III.4.2. The general approach to "damage".

87. The product liability regime established by the Directive 85/374/EEC compensates for personal injury, including fatal injury and, with certain imitations, for property damage (cf. Article 9 PLD). However, it does not compensate for losses resulting from infringements to the rights of personality, pure economic loss, and pure emotional harm, i.e., injury to feelings

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[22] «*This Directive lays down common rules on the liability of economic operators for damage suffered by natural persons caused by defective products*».
[23] See §§ ____.

which is unrelated to personal injury or to the infringement of a personality right. The issue of recoverability for such losses is left to national provisions.

88. The "PLD Proposal" follows a similar pattern and, as an important novelty, it includes "data" understood, as defined by the Regulation (EU) 2022/868[24], as «*any digital representation of acts, facts or information and any compilation of such acts, facts or information, including in the form of sound, visual or audio-visual recording*».
89. Differently from the approach followed in 1985 under which the notion/scope of "damage" was addressed by specific separate provision (Article 9 of the PLD), the Commission's proposal for the revised directive moves this key factor to the list of definitions. However, under the "12.11.2023 Parliament's PLD version", which positively adds compensation as an aim of the directive (Recital 1 «*and is aimed at providing compensation for such damage*»), the suggested approach is modelled similarly to the 1985 PLD, hence there is a separate provision addressing the notion of "damage" (Article 5a, «*Damage*»). In spite of these differences among the versions of the "PLD Proposal", both the PLD and the recent proposals confirm the EU legislator's minimal approach to the issue of damages/recoverable losses/*quantum* whenever liability regimes and compensation are taken into consideration for approximation purposes. Such approach remains agreeable nowadays, but it would deserve some general exceptions towards the development of higher standards of redress protection of the individuals. Moreover, also in the light of recent judgments by the Court of Justice of the European Union expanding the scope of compensation for non-pecuniary losses in relation to the protection of right to privacy[25] and for the sake of coherence, we disagree with the wording of the pending proposals in relation to damage/damages as they may give rise to a considerable risk of reducing the protection granted by way of compensation for damages whenever there is not a proper personal injury, but forms of emotional/moral distress "only".

III.4.3. The need to clarify and assert the recoverability of 'non-pecuniary loss' in the context of the application of the Directive.

90. Generally, "damage" and "damages" are different in meaning: "damage" means the "legal loss", "violation", "harm", "infringement" or "breach" of a legal - material or immaterial - right or good, irrespective of the consequential, pecuniary or non-pecuniary, losses caused by the violation; on the other hand, "damages" means a pecuniary, or monetary compensation in terms of money for the harm suffered, which can be awarded for the – pecuniary and non-pecuniary - losses. A "material damage" (or "material infringement/violation) may give rise to both pecuniary and non-pecuniary losses, as also an immaterial one would do. Reference to material and non-material damage may generate confusion.
91. Article 9 of the PLD still in force does not seem to precisely follow the above distinction among "damage", "damages" and "losses", this with reference to its paragraph 2 stating that the directive shall be without prejudice to national provisions relating to «*non-material damage*».
92. The "PLD Proposal" generates even more confusion as to the use of above expressions, since it provides for the following notion of "damage" at Article 4 (6): «*'damage' means material losses resulting from* [it follows a list of violations including damaging events affecting

[24] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (OJ L 152, 3.6.2022, p. 1).
[25] See *Österreichische Post*, C-300/21, ECLI:EU:C:2023:370, and *Natsionalna agentsia za prihodite*, C-340/21, ECLI:EU:C:2023:986.

immaterial values like life and personal injury]». Whilst under Article 9 (1) of the PLD one could argue that "damage" actually means the infringement of a right/good, under the "PLD Proposal" it looks that "damage" means any consequential "material loss" arising from a violation among the ones listed under the same Article 4 (6), not the harm itself, this contrary to the general notion of "damage"[26].

93. Moreover, as regards to recoverable losses, the "PLD Proposal" seems to refer exclusively to pecuniary losses when it defines "damage" as "material loss" [cf. Article 4 (6) "PLD Proposal"). The only reference made to non-pecuniary loss ("non-material damage") is in Recital (18) which explains that «*this Directive should not affect national rules relating to non-material damage*», which reproduces the last sentence in current Article 9 of "PLD". Accordingly, the "PLD Proposal" not only insists on, but also makes it clearer that the only losses that are imposed at the level of uniform law as being recoverable are the material ones. Therefore, the prospects of recoverability of "non-material damages" are entirely left to the national laws.
94. Same criticisms as above can be raised in relation to Article 5a of the "12.11.2023 Parliament's PLD version".
95. Firstly, this approach to compensation is not ideal at all for a directive, like the future PLD, aiming at (see Recital 8 of the Commission's proposal) creating «*a high and uniform level of consumer protection*», including compensation as added by the "12.11.2023 Parliament's PLD version" to Recital 1 under which the directive is also «*aimed at providing compensation for such damage*».
96. Despite the approximation occurred in the last decades, different approaches to non-pecuniary loss still exist across Europe, and for this reason it is welcome, according to PEOPIL's constant policy[27], that the EU abstains from regulating compensation for non-pecuniary loss. However, as further examined below[28], even if in general terms harmonisation of the law of damages is not feasible nor desirable yet, full compensation for not only pecuniary losses, but also non-pecuniary losses should be stated as a general minimum principle of the directive, this also according to the case-law of the Court of Justice acknowledging compensation for non-pecuniary losses including pain and suffering as well as emotional distress in a wide range of cases[29].
97. The effective protection of fundamental rights including right to health, to family relationships, to personality, to property, to access to justice granted by the Charter of the Fundamental Rights of the European Union calls for not leaving to the Member States the choice between allowing or denying full compensation for non-pecuniary losses arising from the infringements of such rights.
98. Besides the developments within the EU law and the Court of Justice's case-law as well as within the national laws towards a clear expansion of the scope of compensation to the recoverability of non-pecuniary losses, one may also add that the recent Article 10 (16) of EU Regulation 2017/745 of 5 April 2017 on medical devices does not limit the notion of compensation to material damage only, thus it does not exclude from the orbit of EU law the right to claim for non-material damages («*Natural or legal persons may claim compensation*

[26] This is confirmed also by other linguistic versions of the "PLD Proposal". For example, under the Italian version "*danno*" (that under Italian law means either an infringement or a consequential loss or an award) is defined "*perdite materiali derivanti da*", i.r. "losses", not violations.
[27] See _____
[28] See para. ____.
[29] See para. ____.

for damage caused by a defective device in accordance with applicable Union and national law»).

99. Accordingly, it would be extremely desirable that:
    - as it is now the approach in many areas of law by the Court of Justice of the European Union[30], the new directive should make it clear that the recoverability of non-pecuniary losses shall be made available by the Member States at least in personal injury and death cases, but hopefully also whenever there is an infringement of a personality right[31] or a violation of a property right, that is something that may take place in cases where loss or corruption of data take place or a good/property with a particular sentimental value is damaged, as well as in "false positives", "near miss" and "fears of future injuries" cases[32];
    - such protection in terms of compensation should be granted also in relation to the psychological/emotional/moral consequences arising from the violation of above rights even if such psychological/emotional/moral conditions do not amount to a recognised psychiatric disorder.

100. In practical terms, in order to have binding effect, not only Recital (18) of the "PLD Proposal" should clearly state that when applying the new PLD every Member State should compensate "non-pecuniary loss" " (instead of the so-called "non-material damage") in the above situations, but this provision should be included in Article 2 (3) of the Proposal.

101. (a) it means that when applying the new PLD every Member State should compensate non-pecuniary loss which is consequential to death or personal injury or to the infringement of a personality right

102. The effective protection of the fundamental rights granted by the Charter of the Fundamental Rights of the European Union calls for not leaving to the Member States the choice between allowing or denying full compensation for non-pecuniary losses arising from the infringements of such rights.

103. Nevertheless, PEOPIL is also fully aware of the political difficulties with expanding the scope of compensation at the level of uniform rules.

104. Therefore, as a second option to the above indications PEOPIL suggest that the new PLD should clearly state [33]:
    - that compensation for non-pecuniary losses shall take place in each Member State under the same conditions as in purely domestic claims, this according to the principle of non-discrimination;
    - that the minimum standards of the PLD are without prejudice to higher levels of protection in each Member State, this by way of a binding "non-regression clause" included in the body of the new directive[34].

105. Finally, the non-pecuniary losses here under examination are intended as consequential prejudices consisting of human reactions to an adverse unlawful event. This category has nothing to do with punitive damages and exemplary damages which are meant to address the specific kind of conduct of the liable person whenever it is particularly serious also in terms of social blame.

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[30] See para. ____.

[31] Human dignity and personality rights are particularly at risk in the digital age due to the use of new technologies. It would not make too much sense to expand the future PLD to new technologies and to exclude one of the most relevant scenarios of infringements.

[32] As to these last three categories of cases see below § III.4.6.

[33] See § III.4.8.

[34] As to this kind of clauses see AG's opinion – para 54 onwards – in *Mangold*, case C-144/04, ECLI:EU:C:2005:420.

106. In relation to this last category, at this stage PEOPIL accept that punitive damages and exemplary damages are not to be addressed by the future PLD and should remain a matter to be dealt by national laws. It is only in general terms and for the purpose of future debates that PEOPIL consider that the protection of individuals from defective/hazardous products may also benefit from the recognition of the seriousness of the conduct as a factor to be taken into consideration for the purpose of granting awards whenever a fundamental right, including the right to property, is infringed due to a conduct of this kind. In particular, punitive damages or at least aggravated damages (non-pecuniary losses/moral damages aggravated by the particular seriousness of the conduct of the offender) may contribute to disincentive large scales economic strategies aiming at putting into circulation and/or keeping on the market unsafe products likely to negatively affect large numbers of the public.

III.4.4. Mental health: critical reference to the "medically recognised harm to psychological health" in relation to personal injury and death cases.

107. In relation to the personal injury cases and fatal accidents the "PLD Proposal" introduces the reference to the «*medically recognised harm to psychological health*» [Article 4 (6) (a) of the Commission's version; Article 5a (1) of the "12.11.2023 Parliament's PLD version"), this «*in the interests of legal certainty*» (Recital 17), a reference which may also affect the welcome extension by the Proposal of the list of relevant infringements and protected goods/rights under the revised directive.

108. Unfortunately, no legal certainty would be attained by introducing the above category since, first of all, it is not clear whether the Proposal aims at limiting or expanding the redress protection of "psychological health". One may note that by using the word "including" the proposal is not being restrictive, but rather the opposite. Nevertheless, under the "12.11.2023 Parliament's PLD version" Recital 17 adds that the damage to psychological health is the one «*certified by a court ordered medical expert, including psychologists, and limited to serious adverse effects on the victim's psychological integrity of such gravity or intensity that it affects the victim's general state of health and cannot be resolved without therapy or medical treatment, taking, in particular, the International Classification of Diseases of the World Health Organisation into account*». This addition indicates a restrictive approach.

109. Leaving aside that the expression here under scrutiny is extremely vague and a-technical (by the way it is not clear at all whether reference is made to the World Health Organization's definition of "health"[35]) and noting that there a huge difference among "harm" and "damage" as consequential prejudices (temporary or permanent negative alterations of the mental conditions of the victim), it seems that reference to the notion of "medically recognised harm" is not as such as extending, as presumably aimed by the Commission, the

[35] The WHO constitution states: «*Mental health is a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community. It is an integral component of health and well-being that underpins our individual and collective abilities to make decisions, build relationships and shape the world we live in. Mental health is a basic human right. And it is crucial to personal, community and socio-economic development. Mental health is more than the absence of mental disorders. It exists on a complex continuum, which is experienced differently from one person to the next, with varying degrees of difficulty and distress and potentially very different social and clinical outcomes. Mental health conditions include mental disorders and psychosocial disabilities as well as other mental states associated with significant distress, impairment in functioning, or risk of self-harm. People with mental health conditions are more likely to experience lower levels of mental well-being, but this is not always or necessarily the case*» (see "*Mental health*", *who.int*). A relevant implication of this notion is that "mental health" is more than just the absence of mental disorders or disabilities.

scope of redress protection of injured persons to higher levels; instead, if confirmed, it may open the gates to at least four possible restrictions:

- the first is that violations of "psychological health" or, as differently put, of the emotional wellbeing of the injured party would not be any longer relevant for the purposes of configuring a "personal injury";
- the second is that within the personal injury cases any psychological impact on the victim, who sustains a bodily injury, not amounting to a proper "psychiatric damage" may not give rise to a recoverable (non-pecuniary/moral/emotional) loss; in other words, the expression here under scrutiny may construed as limiting the scope of consequential non-material damages recoverable under the applicable national law granting compensation for such kind of losses in (bodily) personal injury cases;
- the third is that - in relation to fatal accidents and accidents permanently injuring a family member - secondary victims not suffering a medically recognised mental illness may be prevented from claiming for any damages or, alternatively, for non-pecuniary losses not amounting to such level of seriousness[36];
- under the fourth potential scenario outside personal injury/death cases one may object that any kind of psychological damage, also including the medically recognised ones, would not be recoverable under the revised directive with the draconian consequence that there would not be any recoverable non-pecuniary loss in such cases.

110. The amendments proposed to the original Commission's text by the Committee on the Internal Market and Consumer protection and the Committee of Legal Affairs (European Parliament, Draft Report, 5 April 2023) do not seem to limit the risk of such potential restrictions. It is true that the expression "medically recognised damage to psychological health" is moved from the text to the recital; nevertheless, there is not any change as to the conception of the level of compensatory protection.

111. It should also be noted that there is a relevant mistake: under the said Draft Report (Recital 17) what needs to be assessed is «*an effect on the victim's psychological health that affects the victim's general state of health as confirmed by a court-ordered medical expert*». Apart from the confusion shown by the Draft Report as to the medical and legal categories concerning mental consequences of an accident, the requirement of a court appointed expert does not take into account that not all Member States contemplate the involvement of court-ordered experts.

112. As noted above, at its Article 5a (1) the "12.11.2023 Parliament's PLD version" not only brings back to the body of the future directive the expression "medically recognised damage to psychological health", but also increases the restrictive features of this reference.

113. Accordingly, PEOPIL insist that in order to grant proper protection to primary and secondary victims reference should be made to "damage to mental health" only without limiting the scope of this category with further specification. Moreover, "mental health" should be intended according to the broad and agreeable definition provided by the World Health Organization.

114. There is a further argument against the requirement of a "medically recognised psychological effect": contrary to the declared scope of the new directive, this requirement provides for a rule negatively affecting both the right to compensation and the recoverability of non-pecuniary losses arising from harm to mental health and the emotional sphere. We do not think there is proper ground for such intervention, in particular given the choice to entirely

[36] Generally, reference is made to the loss of love, companionship, comfort, care, assistance, protection, affection, society, and moral support.

leave any issue concerning "non-material damage" to national laws. Moreover, although under the future PLD it will be national laws and courts who will continue to be the ones to determine and assess the non-material damages/losses, additional requirements like the one here under scrutiny that may be imposed by the directive, and which are not mandatory requirements under the national laws for other cases, may influence the national courts and may lead to application of such more stringent requirements to other - non product liability - cases as well.

115. If the limit to a "medically recognised psychological effect" should be maintained, nevertheless the new directive should make it clear that this expression cannot be construed as putting a limit on national laws against the compensation for non-pecuniary losses related to the emotional/moral consequences of a bodily injury or the death/impairment of a loved person, or related to the violations of other fundamental rights. It should also be avoided any reference to "court ordered medical experts" since this is a matter of procedural/evidence law that is dealt with differently among Member States.

116. Finally, the scenarios of damage to mental health that individuals may suffer from their interactions with humanoid AI robots and systems at home or in the working environment is worth of being addressed by the revised directive. PEOPIL considers that this issue is extremely important and calls for further investigation.

III.4.5. Emotional harm caused by defective products: "near miss", "fear for an injury" and "false positives" cases.

117. A defective product may also cause an "emotional harm", which refers to situations of anxiety, anguish, frustration, that are not consequential upon personal injury or property damage (pure emotional harm or stand-alone emotional harm).

118. Accordingly, the list of violations relevant for the purposes of the new PLD should also encompass "emotional harm" – not amounting to a personal injury – even though we may accept that this scenario is restricted to some specific cases, as also admitted by a considerable number of Member States and in US by the *Restatement (Third) Torts*, Chapter 8 («*Liability for emotional harm*»), §§ 45 and seq., that allows compensation for emotional harm in various cases including intentional or reckless infliction of emotional harm and the case where an actor, by way of a negligent conduct, causes an emotional harm to another by placing the other in danger of immediate bodily harm, or provokes fears for a future injury.

119. In particular, the following examples should be taken into account.

120. "Near miss" (or "immediate danger") cases. An airplane suffers a serious breakdown in mid-flight due to a defect in one of its engine parts. The failure causes the plane to plunge into the void from an altitude of 20,000 to 2,000 feet in 10 minutes without the pilot being able to control it. At the last moment the pilot manages to control the plane, take flight and finally land at the destination airport. The 180 passengers suffered terrible anguish during the 10 minutes they thought they were going to die. Anguish created by fear for their lives during the time passengers have been in extreme danger to die should be recoverable, even if, finally, they have not suffered any personal injury - either bodily or mental injury - or property damage.

121. "Fear of future injury" cases. A first set of cases pertains to those individuals who have been exposed to toxic substances, to some infectious agents or noxious materials (for example those containing asbestos) or cancerogenic devices (for example breast implants) and who are at risk of future personal injury or disease. A second category encompass the anguish for the

risk of suffering from the harm to other rights, like for example the fear experienced by a data subject with regard to a possible misuse of his or her personal data by third parties as a result of the vulnerability of a technological device[37].

122. “False positives” cases. These cases are similar to the last one. A goes to doctor B to take a test to determine whether he has cancer. The products used to carry out this test are defective and due to these defects, the test gives the result that A suffers from terminal cancer and that he only has three months to live. After a month of terrible anguish, A decides to undergo two additional tests with doctors C and D, which show that she does not suffer from cancer but from a disease that is curable and that does not put her life at risk. Anguish created by false diagnosis of a serious illness that the injured party did not actually have and that has been caused by the defectiveness of a product used for the diagnosis should be recoverable.

123. According to the principles of non-discrimination and non-regression, if compensation for non-pecuniary loss consisting of emotional distress is provided under the applicable law, then it shall be compensable according to the future PLD.

III.4.6. Property damage and the need to severe the last link with consumer law.

124. In the case of damages to property, Article 4 (6) (b) of the “PLD Proposal” addresses compensation for damage to the product itself and a product damaged by a defective component of that product, and property used exclusively for professional purposes.

125. Whilst PEOPIL consider that the first two exclusions may appear somehow justifiable (for example in order to prevent a possible circumvention of the contractual rules regarding warranties through product liability rules), in relation to the third exclusion, although the rule simplifies the rule of the current Article 9 (b) (i) and (ii) of the PLD and does away with the difficulties posed by a mixed private/professional use, we consider that is does not go far enough and should not exclude property for professional purposes. Product liability is no longer a set of rules based on the fact that «*protection of the consumer requires that all producers involved in the production process should be made liable*» (Recital 4 Directive 85/374/ CEE). Probably it has never been, since the exclusion of damage to property for professional purposes or mixed use have always been the only link of its rules to consumer law. Moreover, the exclusion of such damage is no longer justified when the CJUE has recognised that consumer protection is not the *ratio legis* behind the Directive in cases such as C-183/00; C-52/00 and C-154/00, where it has clearly taken the position that this is a ‘maximum Directive’, which does not allow Member States to increase the level of protection it offers to injured parties. PEOPIL considers that the Commission should now culminate this development by including damage to property for personal purposes in the scope of application of the Directive.

126. Finally, as regards property damage PEOPIL welcome the abolition of the 500,00 Euro limit, which as is well known created a certain confusion at the time of its implementation, when some Member States interpreted as a threshold which allowed compensation in full when it has been exceeded, whereas in others it was understood as a franchise which was always deductible from the compensatory amount.

127. The industry has reacted to the 500,00 Euro threshold currently provided by Article 9(b) PLD by supporting its reinstatement on the ground that such limit would be fundamental to prevent a backlog of small claims and avoid negative consequences in terms of insurance

[37] The Court of Justice of the European Union confirmed the recoverability of the “non-material damage” consisting of this fear arising from the infringement of GDPR: see *Natsionalna agentsia za prihodite*, C-340/21, ECLI:EU:C:2023:986.

coverage. Their removal completely undermines the goals of consumer protection. For the industry there would be evidence showing the effectiveness of the threshold. PEOPIL disagree with this representation: as a matter of facts, threshold like this kind do not contribute to the prevention of mass torts consisting of putting into circulation products generally causing small damages only (maybe with only few severe cases whose costs are balanced by the existence of the thresholds and the profits gained).

III.4.7. Damage to data: a positive inclusion but with challengeable restrictions.

128. PEOPIL find it positive the inclusion of "loss or corruption of date" (art. 4 (6) c PLD Proposal) into the notion of recoverable damage, this in particular in the light of the new risks generated by the digital revolution. It is well known that the operation of AI-systems may give rise to considerable pecuniary losses and non-material damages (in some cases amounting to relevant psychiatric impairments) for incidents where data or digital content are destroyed, deleted, corrupted, or made unreadable.

129. Losses can be more substantial if data or digital content are used in the business context, where a data loss event may affect day-to-day operation and the general functioning of an enterprise. Moreover, pecuniary consequential loss resulting from data loss, such as damage to business reputation and costumer loss, plus the expenses needed to reconstruct the lost data, can be enormous. However, restricting the damage to the data not used exclusively for professional purposes means depriving it of practically any effect, since it would confine its applicability to pecuniary loss resulting for loss or corruption of data used for personal purposes, which tend to be negligible, and to the so-called 'sentimental value', attached to person-al data such as photos and recordings, which in some European countries is understood as a pecuniary value of affection where in other qualifies as a non-pecuniary loss[38].

130. PEOPIL oppose Article 5a (1) (c) of the "12.11.2023 Parliament's PLD version" where it limits the application of the future PLD whenever the «*material loss*» arising from the destruction or irreversible corruption of data does not exceed EUR 1000. Apart from the circumstance that it remains unclear what constitutes a "material loss" for the purposes of the "PLD Proposal", it is likely that the vast majority of infringements arising from loss or corruption of natural persons' data will cause them immaterial losses only. This scenario may occur also in relation to violations on large scales. Therefore, in such cases the Parliament's proposal would amount to a complete denial of protection, a denial which would go against the reality itself of the damaging events that may occur in this area. This would negatively affect if not entirely frustrate the entire scope of the new protection pursued by the proposal where it addresses the harms consisting of loss or corruption of individuals' data.

III.4.8. PEOPIL conclusive suggestions on the categories of "damage" as violation of rights/goods and "damages" as recoverable consequential losses.

131. Conclusively, PEOPIL suggest the following amendments:

PEOPIL proposal for amending **Article 5a («*Damage*») of the "12.11.2023 Parliament's PLD version"**

[38] See Helmut Koziol in *Digest of European Tort Law*, Vol 2: Essential Cases on Damage, 14/30, pp. 749-752.

1. For the purpose of this Directive, ‘damage’ means:

(a) death or personal injury, including damage to mental health;

(b) damage to, or destruction of, any property, except:

(i) the defective product itself;

(ii) a product damaged by a defective component of that product that is integrated into, or inter-connected with, a product by the manufacturer of that product within that manufacturer’s control;

(c) destruction or irreversible corruption of data;

(d) emotional harm arising from: (i) intentional or reckless conducts aimed at causing emotional harm to an individual; or (ii) a product placing a person in danger of an immediate potentially serious personal harm; or (iii) a product causing concrete fear for a future potentially serious injury; or (iv) a product which is especially likely to cause serious emotional harm.

2. “Mental health” means a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community. It is an integral component of health and well-being that underpins individual and collective abilities to make decisions, build relationships and shape the world one lives in. Mental health conditions include mental disorders and psychosocial disabilities as well as other mental states associated with significant distress, impairment in functioning, or risk of self-harm.

3. ‘Compensation for damage’ refers to both consequential pecuniary loss and non-pecuniary loss resulting from a relevant damage within the meaning of paragraph (1) including the losses suffered by secondary victims as a consequence of the primary victim’s death or personal injury within the meaning of paragraph (1) point (a), or the primary victim’s exposure to an immediate risk of a potentially serious personal injury within the meaning of paragraph (1) point (d).

4. This Article shall be without prejudice to national provisions relating to compensation for pecuniary and non-pecuniary losses. According to the principle of non-discrimination compensation for pecuniary and non-pecuniary losses in the above cases shall take place in each Member State under the same conditions as in purely domestic claims. The minimum standards provided by this Article shall not constitute valid grounds for reducing levels of protection by way of compensation in each Member State.

III.6. The liability regime: strict or defect (fault)-based?

132. Early and present comments from those representing producers stress that they consider the revision will extend the scope of claims that can be brought, the range of damages that can be recovered and generally make it easier for consumers to prove their case. This of course reflects the intention of the European Commission whilst at the same time giving producers legal certainty and predictability about the liability risks, they face when doing business. At first glance, in terms of making it easier for victims to bring claims, it may be said that all that glitters is not gold.

133. PEOPIL appreciate the amendments to the 1985 PLD suggested by the Commission. Nevertheless, there are various points to be considered for a different and more courageous review of the 1985 PLD, especially if the aim pursued by the present EU legislature is to establish not minimum rules on liability for defective products, but a uniform regime excluding the application of national schemes granting more protection to the victims. In particular an opportunity to remove the deficiencies in victims' routes to remedy that have occurred over the last 40 years should be uppermost in the reforms.

III.6.1. Strict liability or defect (fault)-based liability?

134. Recital 2 of the "PLD Proposal", states that «*Liability without fault on the part of the relevant economic operator remains the sole means of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production*». From the reading of both the 1985 PLD and the "PLD Proposal" it comes out that they fail to establish a liability regime that can be defined as "strict".

135. In most cases reference to strict liability as "liability independent of fault" is indeed more a myth than reality. In fact, in the vast majority of regimes, that are labelled under the category of "strict liability", for the purposes of assessing liability it is required or implied evidence of a defect, a malfunction, a wrongful behaviour or a non-performance of a duty attributable to the defendant. Requirements of this kind put these liability regimes outside the "pure" strict liability class, under which, once the relevant material causal link is established, generally the defendant remains without any kind of exemptions from liability ("absolute strict liability")[39]. Consequently, classifying the 1985 PLD regime as well as the proposed scheme under the new directive as providing for "pure strict liability" is somehow misleading.

136. Whenever a subject may escape liability on the ground of the unpredictability or unavoidability of the accident due to its/his/her limited knowledge and/or control at the time the damaging thing has been put in place or into circulation, then there is still a margin, even if small, for legal reasoning based on fault or wrongful behaviour or non-compliance, irrespective of the circumstance that such standards are conceived in terms of lack of diligence or prudence or whatsoever.

137. In the new proposal one may find evidence of this margin in the many points listed below in this and following paragraphs.

138. This is not to say that PEOPIL oppose the existence of this margin. On the contrary, even though at the same time one may think of a fund or insurance for the benefit of victims of products with unavoidable and unpredictable damaging effects at the time they were put into circulation, PEOPIL support the manufacturers and other economic operators' right to prove that they have acted in good faith and adopted all the optimal precautions in order to avoid the damaging event. The fact is that the recurrence of this margin proves that the industry and the politicians supporting the business stakeholders are promoting a misleading representation whenever they say that manufacturers are and will be subject to "strict liability" like they are exposed to a form of "absolute liability" without any kind of defence. This label is simply misleading, especially when used for political/lobbying purposes, including for supporting broad exemptions from liability, caps on compensation or rigid time limits.

[39] Strict liability is a continuum and liability is "stricter" depending on the defences available to the defendant (force majeure, contributory negligence, damage caused by a third party, etc). "Absolute strict liability" exists only when the defendant has no defence at all, which can happen in very rare cases such a damage caused by nuclear energy.

139. What PEOPIL disagree with in relation to both the 1985 PLD and the new proposal concerns some features of that margin, in particular in relation to the notion of defectiveness, the risk development defence, preemption defence and the ways the burden of proof is distributed among the parties to the litigation, in particular in relation to causation issues.

140. It is worth mentioning here that on 21 November 2019 the European Commission's Expert Group on Liability and New Technologies – New Technologies Formation ("NTF") published its *Report on Liability for Artificial Intelligence and other emerging technologies*[40], where it also suggested the adoption of a strict liability model much more stringent than the one then provided by the "PLD Proposal":

> **6. Producer's strict liability ([13]–[15])**
>
> **[13] Strict liability of the producer should play a key role in indemnifying damage caused by defective products and their components, irrespective of whether they take a tangible or a digital form.**
>
> **[14] The producer should be strictly liable for defects in emerging digital technologies even if said defects appear after the product was put into circulation, as long as the producer was still in control of updates to, or upgrades on, the technology. A development risk defence should not apply.**
>
> **[15] If it is proven that an emerging digital technology has caused harm, the burden of proving defect should be reversed if there are disproportionate difficulties or costs pertaining to establishing the relevant level of safety or proving that this level of safety has not been met. This is without prejudice to the reversal of the burden of proof referred to in [22] and [24].**

141. One may question why the rule no. 15 under the above Expert Group's model should not apply to traditional products too as it is difficult to see a good reason to distinguish between, just to make an example, pharmaceutical products and digital products.

III.6.2. The revised updated notion of defectiveness: is it entirely satisfactory?

DEFECTIVENESS	
Directive 85/374/EEC	**PLD Proposal**
Article 6	Article 6 Defectiveness
1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation.	1. A product shall be considered defective when it does not provide the safety which the public at large is entitled to expect, taking all circumstances into account, including the following: (a) the presentation of the product, including the instructions for installation, use and maintenance; (b) the reasonably foreseeable use and misuse of the product;

[40] The Commission tasked the NTF with establishing the extent to which liability frameworks in the EU will continue to operate effectively in relation to emerging digital technologies (including artificial intelligence, the internet of things, and distributed ledger technologies).

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.	(c) the effect on the product of any ability to continue to learn after deployment; (d) the effect on the product of other products that can reasonably be expected to be used together with the product; (e) the moment in time when the product was placed on the market or put into service or, where the manufacturer retains control over the product after that moment, the moment in time when the product left the control of the manufacturer; (f) product safety requirements, including safety-relevant cybersecurity requirements; (g) any intervention by a regulatory authority or by an economic operator referred to in Article 7 relating to product safety; (h) the specific expectations of the end-users for whom the product is intended. 2. A product shall not be considered defective for the sole reason that a better product, including updates or upgrades to a product, is already or subsequently placed on the market or put into service.

142. One may ask why there is any need for keeping reference to the notion of defectiveness whilst the real issue is whether a product may be or not be unsafe and potentially damaging.
143. The Commission's choice was to maintain the traditional approach centred around the concept of defectiveness instead of "dangerousness", "unsafeness" or "harmfulness", however by adapting it to the new scenarios of products in the digital/AI world.
144. Undoubtedly, the Commission has positively adjourned the notion of defectiveness by taking into account that digital products in general and AI-systems in particular are subject to regular updates not only to improve their utility, but also, at least in theory, to improve their safety. For this reason, it would not be appropriate to stop the analysis of defectiveness at the time when the product is put into circulation. Rightly, liability of the manufacturer is extended by the "PLD Proposal" beyond this moment and is to be decided according to the safety expectations that existed when the accident occurred.
145. In addition to the circumstances established in the current Directive (such as the presentation of the product and the use that could reasonably be expected), Article 6 of the Proposal mentions, the presentation of the product, including the instructions for installation, use and maintenance, the reasonably foreseeable use and misuse of the product, and the effect it may have on the product of any ability to continue to learn after deployment. It also refers to the effect on the product of other products that can reasonably be expected to be used together with the product, and safety requirements, including cybersecurity, and any intervention by a regulatory authority or by other economic operators on safety matters.
146. Finally, it also takes into account that the manufacturer can maintain control of the product after it has been placed on the market in order to replace, in these cases, the old moment of "putting into circulation" by the loss of control of the product by manufacturer.

147. These additions are all positive in the view of higher standards of product liability for the benefit of the victims. However, as further addressed below (see points _____), this expansion of the notion of defectiveness from the moment of “putting into circulation” to the time of “losing control” seems to be restricted by the notion of the “manufacturer’s control” as provided by Article 4 (5) of the “PLD Proposal” («*‘manufacturer’s control’ means that the manufacturer of a product authorises a) the integration, inter-connection or supply by a third party of a component including software updates or upgrades, or b) the modification of the product*»), even though, as already reported above, this concept has been expanded by the “12.11.2023 Parliament’s PLD version” («*‘manufacturer’s control’ means that the manufacturer of a product performs or, with respect to the actions of a third party, explicitly authorises or consents to a) the integration, inter-connection or supply by a third party of a component including the specific software updates or upgrades, or b) the modification of the product, including substantial modifications*»). Nowadays, if we want to actually protect individuals from serious infringements of their fundamental rights (firstly, the rights to health, physical/mental integrity, life, dignity, right to family relationships, privacy and respect for private life) and we want to stick to the defect criterion, we should accept that defectiveness may include the manufacturer’s choice to leave the product capable to develop itself into a thing causing harm to humans after the moment it/he/she has lost the actual control. In other words, the definition of “manufacturer’s control” provided by the Proposal may not match with the AI systems’ abilities to evolve (*rectius* decline) autonomously towards dangerous paths, which is a problem that is becoming more evident with the recent developments of generative AI (GenAI). Apart from the fact that together with Article 10 (1) (e) of the Proposal this proves that the proposed regime is far away from being a “strict liability” one (it may become necessary to assess how the control was performed), this notion is challengeable also from the fault perspective since it may not enable the sanctioning of the manufacturer’s choice to put into circulation artefacts/systems that are not designed in such a way to be prevented from causing injuries to humans[41].

148. One may object to these concerns that the risks connected with reference to the “manufacturer’s control” in relation to new technologies and, in particular, AI systems is properly addressed by Article 6 (1) (c) of the “PLD Proposal” where it includes among the factors to be considered for a product to be defective «*(c) the effect on the product of any ability to continue to learn after deployment*». The “12.11.2023 Parliament’s PLD version” suggested to amend this provision with the following version: «*(c) the effect on the product of any ability to acquire new features or knowledge after it is placed on the market or put into service*».

149. We agree that this is a positive step forward. However, we also believe that there should be a clear statement by the future directive providing for the irrelevance of the manufacturer’s control for the purposes of the notion of defectiveness whenever the product was enabled by the manufacturer to autonomously develop, also by way of inputs from third parties, into a damaging item. The manufacturer’s acceptance of this possibility should make the moment in time when the product left the actual control of the manufacturer irrelevant.

150. Accordingly, we suggest to amend Article 6 (1) (e) by adding the following sentence in bold imposed by the expansion of the notion of product to AI systems:

[41] We will get back to this concept below at points ____ when addressing the issue of “human fault” under the “AILD Proposal”.

> (e) the moment in time when the product was placed on the market or put into service or, where the manufacturer retains control over the product after that moment, the moment in time when the product left the control of the manufacturer; **the moment that the product left the manufacturer's actual control may be irrelevant whenever the manufacturer enabled the product to autonomously develop itself, also by way of inputs from third parties, into a damaging item**;

151. We also agree with Article 6 (1) (g) of the "PLD Proposal", although in line with Recital 24, it should be made it clear that it also refers to mandatory and voluntary recalls. In our view, reference to such cases for the purpose of assessing product defectiveness would not discourage manufacturers from voluntarily recalling products[42]. Accordingly, we agree with the amendment proposed by the "12.11.2023 Parliament's PLD version" («*(g) any **recall of the product or any other relevant intervention** decided by a regulatory authority or by an economic operator referred to in Article 7 relating to product safety*»).

152. Moreover, it is arguable whether the notion of defectiveness should still refer to the 'consumer expectation test' only and whether the benchmark for these expectations should be linked to human performance or to technical standards.

153. Until now, the wording of Article 6 of Directive 85/374/EEC suggests an interpretation in the sense of the 'consumer expectations test', which focuses on consumers' safety expectations of the public at large or, occasionally to a targeted group of consumers. Article 6 of the "PLD Proposal" adopts the same point of view when it establishes that «*a product shall be considered defective when it does not provide the safety which the public at large is entitled to expect*». However, this language cannot be considered as a final decision against the alternative 'risk-utility test', according to which, a cost/benefit-analysis should be applied, and the product considered defective if the safety gain from an alternative design is greater than the utility reduction (including increased cost) of that alternative design. This alternative analysis surfaces, for instance, in Recital 22 when it explains that the assessment of defectiveness should involve an objective analysis and that «*the safety that the public at large is entitled to expect should be assessed by taking into account, inter alia, the intended purpose, the objective characteristics and the properties of the product in question as well as the specific requirements of the group of users for whom the product is intended*». A clearer move towards this alternative test would have been welcome, since it is better suited to solve problems involving design defects - which probably will be the most common in this area - and complex technologies.

154. We also appreciate that Recital 22 makes it clear that the assessment of defectiveness should involve an objective analysis and «*not refer to the safety that any particular person is entitled to expect*». The Recital 22 or Article 6 itself should also clarify that "public at large" does not mean the "average person", as this last standard is far away from being objective, reliable and just. Moreover, the Recital should also state that whenever considering the aim of granting safety one should look at the lowest - cultural, educational, intelligent, social - level of the beneficiaries in terms of risk expectations and precautions. Depending on the products one should also consider that "public at large" may use ordinary products in situations of stress or carelessness. Accordingly, PEOPIL agree with the addition of the

[42] For further comments on this issue see below points ____.

reference to possible misuses and oppose the amendment[43] suggested to the original Commission's text by the Committee on the Internal Market and Consumer protection and the Committee of Legal Affairs (European Parliament, Draft Report, 5 April 2023).

155. Moreover, since the AI Act encourages the development of technical standards and endows them with binding effect, if these standards exist in given cases, performance below these standards should lead to the consideration that the product is defective. Moreover, when these standards do not exist, since AI-systems aims at performing much better than human beings, performance below human standards should give rise to a rebuttable presumption of defectiveness.

156. PEOPIL also suggest that the notion of defectiveness, if maintained, should clearly include what in economics and industrial design is called "planned obsolescence" (or "built-in obsolescence" or "premature obsolescence"), which consists of a business policy of planning and/or designing a product with an artificially limited useful life or a purposely frail design, so that it becomes obsolete after a certain pre-determined period of time upon which it decrementally functions or suddenly ceases to function. This approach to the making of products may cause harms of different nature, including personal injuries and fatal accidents. For the purposes of product liability, the claimant should not have the burden of proving the final aim pursued by the manufacture and, in particular, the intentional shortening of either the lifespan of the product and consequently its replacement cycle in order to generate long-term sales volume. It should be sufficient for the claimant to prove the "premature obsolescence" irrespective of the manufacturer's intentionality.

157. The notion of defectiveness should also encompass the case where a device or a system (for example, an app on smartphones, a platform, a software) is designed and/or developed in such a way that it provokes negative effects on utilizers' mental health on a large scale (for example, dependency to such devices or systems, propension towards violent acts or suicidal ideation, addiction to substances or other goods, social behaviours, political, religious or other believes, etc.)[44].

158. Finally, PEOPIL oppose all amendments to Article 6 proposed by the Committee on the Internal Market and Consumer protection and the Committee of Legal Affairs (European Parliament, Draft Report, 5 April 2023) since they would weaken the claimants' protection. However, we positively note that a different agreeable path has been adopted by the "12.11.2023 Parliament's PLD version".

III.6.3. The burden of proof on claimants: the presumption of defectiveness.

BURDEN OF PROOF	
Directive 85/374/EEC	**PLD Proposal**
Article 4	Article 9 Burden of Proof
The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.	1. Member States shall ensure that a claimant is required to prove the defectiveness of the product, the damage suffered and the causal link between the defectiveness and the damage.

[43] «*A product shall be considered defective when it does not provide the safety an average person is entitled to expect and that is also required under Union or national law*».

[44] One may also think about social media platforms fuelling youth mental health crisis by misleading the public about their dangers and knowingly inducing young children and teenagers into an addictive and compulsive use of the same.

	2. The defectiveness of the product shall be presumed, where any of the following conditions are met: (a) the defendant has failed to comply with an obligation to disclose relevant evidence at its disposal pursuant to Article 8 (1); (b) the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred; or (c) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances. 3. The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question. 4. Where a national court judges that the claimant faces excessive difficulties, due to technical or scientific complexity, to prove the defectiveness of the product or the causal link between its defectiveness and the damage, or both, the defectiveness of the product or causal link between its defectiveness and the damage, or both, shall be presumed where the claimant has demonstrated, on the basis of sufficiently relevant evidence, that: (a) the product contributed to the damage; and (b) it is likely that the product was defective or that its defectiveness is a likely cause of the damage, or both. The defendant shall have the right to contest the existence of excessive difficulties or the likelihood referred to in the first subparagraph. 5. The defendant shall have the right to rebut any of the presumptions referred to in paragraphs 2, 3 and 4.

159. Under Article 4 of the 1985 PLD the need to prove a "defect in the product" (i.e. that it did not provide the safety that the public is entitled to expect) and the causal relationship between the identified "defect" and damage already constitutes a considerable burden for the victims of non-AI products ("traditional products"). As to digital and AI artefacts/systems

these requirements would place consumers and, more in general, injured persons in extremely critical situations due to the technological complexity of such products which makes it more difficult to identify both the "defect" and the person or persons responsible for the "defect". Moreover, there are still some substantial discrepancies among Member States as to the application of these prerequisites; as a consequence, in order to avoid further divergences and minimize unrealistic evidentiary burdens, it should be made it clear that, for the purpose of the reversal of the burden of proof on the defendant, it is sufficient for the injured party to allege that the product was "unsafe" and prove that it caused the harm, without the need of identifying the specific "defect" that caused the damaging event.

160. As a consequence, PEOPIL oppose in general the confirmation, by the "PLD Proposal", of the previous approach. However, we accept that it would be too much optimistic a complete U-turn on the fundamentals of the rule now under scrutiny.

161. This being said, even though there are some interesting proposals under Article 9, this provision should be much improved in relation to many aspects. Indeed, the "12.11.2023 Parliament's PLD version" suggests some amendments to Article 9 of the "PLD Proposal" that considerably improve the original proposal by the Commission.

162. As a first example of amendments that should be contemplated, under Article 9 (2) (b) a product is presumed to be "defective" if it can be shown that it does not comply with mandatory safety requirements under either EU or national laws. However, the most obvious suggestion of a product being defective, a product recall, does not seem to create a presumption of defectiveness according to the recitals in the revised directive[45]. Accordingly, we suggest that a recall (or health alert), voluntary or imposed by an authority, must trigger the presumption. In particular, we suggest the following amendment to Article 9 (2) or (3): «*A product shall be presumed defective whenever it is subject to a recall/withdrawal from the market. In such a case, the presumption of defectiveness should be only related to the reason, if any, for which the recall was determined*». This would not deter producers from recalling voluntarily: in fact, in the vast majority of cases voluntary recall amounts to an action that would need to be undertaken anyway in order to avoid not only the occurrence of damages, possibly on a large scale, together with a much more negative impact on the commercial reputation, but also the risk of the removal of insurance indemnity by the producer's insurers. Furthermore, voluntary recalls usually only precede an enforced one anyway. It should also be considered that this would be a presumption only, so the manufacturer and the other economic operators would always be able to overcome it.

163. Moreover, it is unclear how Article 9 (2) (b) - non-compliance with safety requirements - will avoid the same arguments that victims currently face in court.

164. Indeed, it should be the manufacturer or the other economic operators who should give evidence of the compliance, in the absence of such evidence rebuttable presumption of defectiveness of the product, if not of liability itself, should apply.

165. That the claimants need to give evidence of the non-compliance is even more difficult to be accepted in relation to high-risk AI systems, this in the light of the features of such systems (opacity, complexity, etc.)[46] and the stringent compliance duties imposed by the future AI Act on producers/providers of AI systems.

166. As to AI systems it should also be noted that Article 9 (2) does not mention the cases of non-compliance with the requirements set by the future AI Act, like on the contrary Article

[45] In addition, the "12.11.2023 Parliament's PLD version" suggests to amend Recital 24 by specifying that «*Voluntary interventions* [by economic operators] *should, however, not of themselves create a presumption of defectiveness*».

[46] See § ______ below.

4 («*Rebuttable presumption of a causal link in the case of fault*»), paragraph 2, of the "AILD Proposal" does, even though unjustly by putting the burden of proof on the claimant instead of the defendant[47].

167. At least in relation to AI systems either under the future AILD, as examined further below in this paper, as well as under the new PLD the defendants should be the ones who, in our perspective, have to prove compliance with the duties provided by International, EU and national laws, with the consequence that, without this specific evidence, claimants should be entitled to a rebuttable presumption of liability (tis under the AILD; at least of defectiveness in the case of the future PLD). This seems to be the only approach coherent with the aims of the future AI Act.

168. Article 9 (2) (c) provides for a new definition for a defect, that there is an "obvious malfunction" during normal use or under ordinary circumstances, but again experience has shown these types of cases have rarely been the problem for the victims. The problem arises in the so-called standard product (one which is in the form intended by the supplier) where it is argued it is nevertheless defective.

169. We have already seen comment from those representing producers to challenge what could be considered an "obvious malfunction" and their complaint that they think this will bring consumer expectation up to an entitlement that hundred percent of products should be safe at all times. This is certainly an area where the consumer is going to have a very different interpretation to that of the defendant. That will only lead to more litigation which inevitably favours the deep pocketed manufacturer rather than the consumer and the victims in general.

170. Moreover, we suspect that in relation to AI systems cases of "obvious malfunction" will be rare or at least will not represent the majority of cases.

171. Anyway, since the expression "malfunction" may be subject to misunderstanding, our suggestion is to substitute the notion of "obvious malfunction" with the different and more accurate notion based on the objective difference between the product's expected performance and its actual performance (or non-performance).

172. Accordingly, PEOPIL propose to redraft Article 9 (2) (c) as follows:

PLD Proposal	**PEOPIL Proposal**
Article 9 (2) (c)	Article 9 (2) (c)
(c) the claimant establishes that the damage was caused by ~~**an obvious malfunction**~~ of the product during normal use or under ordinary circumstances.	(c) the claimant establishes that the damaging product did not perform as typically or expectable during its normal use or under ordinary circumstances[48].

173. As to AI systems, for the purposes of Article 9 (2) (c) the concept of "performance" may be substituted also with activity/inactivity.

174. Finally, as to the above paragraph 2, we also oppose the suggestion made by the Committee on the Internal Market and Consumer protection and the Committee of Legal Affairs (European Parliament, Draft Report, 5 April 2023) and by the "12.11.2023

[47] See point ______ below.

[48] We also submit the following different but more complex wording for the proposed amendment: «*the claimant establishes that the damage was caused by an objective difference between the product's expected performance and its actual performance (or non-performance) during normal use or under ordinary circumstances*».

Parliament's PLD version" that Article 9 (2) (c) should refer to the "use as intended by the manufacturer"[49] instead of the Commission's reference to the "normal use".

175. Article 9 (4) of the "PLD Proposal" provides for the "excessive difficulty" presumption, another new provision that is also imprecisely worded.

176. First of all, Article 9 (4) (2) provides that «*The defendant shall have the right to contest the existence of excessive difficulties or the likelihood referred to in the first subparagraph*»[50]. This means it is likely to result in a trial within a trial and is unlikely to result in a quicker or cheaper resolution.

177. For this precise reason PEOPIL also oppose the above European Parliament's Draft Report dated 5 April 2023, that proposes to amend the introductory part of the Commission's text of Article 9 (4), by adding that a national court may judge that the claimant faces excessive difficulties only after «*a thorough consultation with experts in the relevant field*». Accordingly, it is positive that the "12.11.2023 Parliament's PLD version" does provides for the same amendment.

178. We also oppose that the same introductory part should be redrafted - as suggested by the above European Parliament's Committees on 5 April 2023 and by the "12.11.2023 Parliament's PLD version" - by adding «*notwithstanding the disclosure of evidence in accordance with Article 8*»: whilst Article 8 should be construed as a right for the claimant to have access to such evidence, the lack of it should put the defendant in a negative position, hence it should give rise to a rebuttable presumption of causation/defectiveness.

179. Instead, it should be taken into consideration the rule proposed by the above quoted European Commission's Expert Group on Liability and New Technologies – New Technologies Formation ("NTF"): «*[15] If it is proven that an emerging digital technology has caused harm, the burden of proving defect should be reversed if there are disproportionate difficulties or costs pertaining to establishing the relevant level of safety or proving that this level of safety has not been met*».

180. Finally, we oppose the following amendment to Article 9 (4) (1) (b) proposed by the said two Committees of the European Parliament on 5 April 2023: «*it is <u>highly</u> likely that the product was defective in such a way that the defectiveness is a <u>highly</u> likely cause of the damage*». Causation in jurisdictions which favour the arithmetical approach (more than a doubling of the risk) has caused consumers to struggle in pharmaceutical and medical device cases. This may offer a route to success where evidence to cement the link between the damage and the product is problematic. Instead, we suggest to refer to the standard "more probable than not" or, at least, the wording "possible".

181. As further examined below, the text of Article 9 (4) (1) (b) suggested by the "12.11.2023 Parliament's PLD version" represent a considerable improvement that PEOPIL fully support.

182. This being said, Article 9 (3) may be the only real benefit to come out of the Commission's initial proposal unless further developments according to the new text of Article 9 (4) (1) (b) proposed by the "12.11.2023 Parliament's PLD version".

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[49] This is the proposed text supported by the "12.11.2023 Parliament's PLD version": «*(c) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use as intended by the manufacturer or under ordinary circumstance*».

[50] The "12.11.2023 Parliament's PLD version" provides for a similar rule: «*The defendant shall have the right to contest the existence of excessive difficulties or the* ***possibility*** *referred to in the first subparagraph*».

183. The Commission text states that «*The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question*».

184. The rule proposed by the Commission, even though as agreeably integrated by the "12.11.2023 Parliament's PLD version" that adds the alternative case «*or where the product belongs to the same production series as a product already proven to be defective*», is far away from being ideal, since it requires the claimant to prove the defect of the product in order to have access to the presumption in question. We strongly believe that this provision would not solve the gaps that currently exist in the protection of injured parties by the burden of proof being by Article 4 placed entirely upon them.

185. One solution may consist of the strengthening of the new rebuttable presumption of causation by basing it on the French concept of "*implication*" (the "involvement" of the product in the accident)[51], even though by keeping this notion connected with the alleged defect (the ground of product liability), and by avoiding imposing on the victim the burden of proving the defect, as follows:

PLD Proposal	**Amendment based on the concept of "*implication*"**
Article 9 (3)	Article 9 (3)
The causal link between the defectiveness of the product and the damage shall be presumed, where it has been established that the product ~~is defective~~ and the damage caused is of a kind typically consistent with ~~the defect in question~~.	The causal link between the **alleged** defectiveness of the product and the damage shall be presumed, where it has been established that the product **was involved in the damaging event** and the damage caused is of a kind typically consistent with **the alleged defectiveness** of the product.

186. However, this solution, as extensively debated in the course of the drafting of this paper, may raise considerable criticisms in relation to the notion of "implication"[52] as well as to the relationship between "general causation" and the grounds of liability.

187. An alternative valid option, which would enable to avoid such criticisms and simultaneously complete Article 9 (3) with a rule more favourable to victims, is provided by the amendments to Article 9 (4) (1) (a) and (b) suggested by the "12.11.2023 Parliament's PLD version":

PLD Proposal	**"12.11.2023 Parliament's PLD version"**
Article 9 (4) (1) (a) (b)	Article 9 (4) (1) (a) (b)
(a) the product **contributed to** the damage; and	(a) **the national court considers that the claimant faces excessive**

[51] See Article 1 of Loi n° 85-677 du 5 juillet 1985 tendant à l'amélioration de la situation des victimes d'accidents de la circulation et à l'accélération des procédures d'indemnisation: «*Les dispositions du présent chapitre s'appliquent, même lorsqu'elles sont transportées en vertu d'un contrat, aux victimes d'un accident de la circulation dans lequel est impliqué un véhicule terrestre à moteur ainsi que ses remorques ou semi-remorques, à l'exception des chemins de fer et des tramways circulant sur des voies qui leur sont propres*».

[52] One may object that the idea of "involvement" goes too far and that it appears in the French *Loi Badinter* for the specific case of road traffic accidents, being this a very significant departure form tort law rules designed only for an area of activity where risks are specifically delimited.

(b) it is **likely** that the product **was** defective or that its defectiveness is a **likely** cause of the damage, or both	**difficulties, due to technical or scientific complexity to be able to prove the defectiveness of** the product **or the causal link between its defectiveness and** the damage**, or both**; and (b) **the claimant establishes, on the basis of relevant evidence, that** it is **possible** that the product **contributed to the damage, and it is possible that the product** is defective or that its defectiveness is a **possible** cause of the damage, or both.

188. If confirmed by the final version of the future PLD, the above rule proposed by the "12.11.2023 Parliament's PLD version" would represent a significant step forward in the protection of victims of defective products.

189. Clearly, one may argue that the presumption of causation or defectiveness, or both, as provided by the "12.11.2023 Parliament's PLD version" at Article 9 (4) (1) (b) should always apply irrespective of any judicial assessment about the excessive difficulties that the claimant may face. Making this rule dependant on the judicial assessment in the course of judicial proceedings is likely to render the application of this presumption uncertain and discretionary.

III.6.4. The exemptions from liability: critical issues and need for amendments to pending proposals.

Directive 85/374/EEC	**PLD Proposal**
Article 7	Article 10 Exemption from liability
Article 7 The producer shall not be liable as a result of this Directive if he proves: (a) that he did not put the product into circulation; or (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or (c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or	1. An economic operator referred to in Article 7 shall not be liable for damage caused by a defective product if that economic operator proves any of the following: (a) in the case of a manufacturer or importer, that it did not place the product on the market or put it into service; (b) in the case of a distributor, that it did not make the product available on the market; (c) that it is probable that the defectiveness that caused the damage did not exist when the product was placed on the market, put into service or, in respect of a distributor, made available on the market, or that this defectiveness came into being after that moment;

(d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the Product.	(d) that the defectiveness is due to compliance of the product with mandatory regulations issued by public authorities; (e) in the case of a manufacturer, that the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered; (f) in the case of a manufacturer of a defective component referred to in Article 7 (1), second subparagraph, that the defectiveness of the product is attributable to the design of the product in which the component has been integrated or to the instructions given by the manufacturer of that product to the manufacturer of the component; or (g) in the case of a person that modifies a product as referred to in Article 7 (4), that the defectiveness that caused the damage is related to a part of the product not affected by the modification. 2. By way of derogation from paragraph 1, point (c), an economic operator shall not be exempted from liability, where the defectiveness of the product is due to any of the following, provided that it is within the manufacturer's control: (a) a related service; (b) software, including software updates or upgrades; or (c) the lack of software updates or upgrades necessary to maintain safety.

190. Currently, Article 7 of the 1985 PLD provides various causes of exemption. The "PLD Proposal" suggests modifying some of them to be better applicable to AI systems. Thus, Article 10 tries now to adapt the language to these different situations. Nevertheless, the final outcome is far away from being entirely satisfactory, also given that the defences under 1985 PLD are all confirmed with minor amendments: the structure and available defences remain intact, hence the revised rules present most of the critical features that already characterise the PLD.

191. First of all, the rule now under Article 10 (1) (c) remains extremely critical since the circumstance that the defectiveness which caused the damage did not exist when the product was placed on the market, put into service or, in respect of a distributor, made available on the market, or that this defectiveness came into being after that moment, should not be sufficient to exempt the defendant from liability whenever the defect in any of these moments

was a known possibility or could have been foreseen. The acceptance of a risk that a product may become defective should prevent the economic operators subject to the PLD from relying on such defence whenever the risk was detectable on the ground of affordable tests or the indications arising from scientific-technical literature.

192. Other situations that should not give rise to an exemption under this defence are the case where the defect originated in any update (either if authorised or made it possible by the manufacturer)[53] and the case where the defect came into being after the moments considered by this rule, but the damaging event could have been prevented by way of a recall campaign or other precautionary measures.

193. Furthermore, Article 10 (1) (c), as proposed by the Commission, is even more critical in relation to the new technologies and, in particular, to AI systems where the defectiveness may develop long after the moments indicated by the proposed rule. The fact that the defect may be attributed to the autonomous development of the AI system (possibly on the ground of inputs from third party) should prevent defendants from relying on such defence, this for the reasons already exposed above[54] and further developed in relation to the AILD proposal and its notion of "human fault" in relation to damages caused by AI systems[55]. In fact, here there might be the manufacturer's acceptance of the risk of putting into circulations items that, as they are designed, may become harmful; such acceptance, which should be subject to a rebuttable presumption against the defendant, should not exempt from liability, at least whenever the manufacturer did not adequately disable the AI system from developing "behaviours" against humans as well as physical and digital environments. On the other hand, one may note that indeed in such case the defect (lack of precautionary measures to avoid harmful activities or omissions) already exists since the design of the product. Whatever is the correct version, in such cases the defence under Article 10 (1) (c) should fail. This limit to the application of the defence now under scrutiny needs to be specified by the future new PLD since the derogations provided by Article 10 (2) are not sufficient to avoid unjust exemptions according to paragraph (1) (c) in relation to AI systems, this in particular in the light of the incorrect requirement that the product is still within the manufacturer's control[56].

194. Anyway, it should be also made clear that Article 10 (1) (c) should not apply whenever the product, as it was originally designed, did not allow the detection of the defect.

195. The amendment to Article 10 (1) (c) proposed by the "12.11.2023 Parliament's PLD version", which adds to the original text «*provided that that defectiveness did not result from any update or supply under the control of that economic operator and was not due to the failure of that economic operator to provide an update as required by Union or national law*», does not solve all above concerns.

196. Instead, we definitely oppose Article 10 (1) (d) of the Commission's "PLD Proposal", that, by confirming word by word the rule under Article 7 (d) of the 1985 PLD, provides that the economic operator goes exempt from liability if the defectiveness is due to compliance of the product with mandatory regulations issued by public authorities. This rule is extremely

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[53] It is true that paragraph 2, point (b), includes among the derogations to the defence under paragraph 1, point (c), the case where the defectiveness of the product is due to software updates or upgrades. Nevertheless, this derogation applies to software updates only, whilst the rule should refer to any kind of updates, including refurbishments. Moreover, the derogation here under scrutiny is limited to the case where such updated was within the manufacturer's control.

[54] See point ______ above.

[55] See point ______ below.

[56] The European Parliament's Draft Report dated 5 April 2023 proposed to amend Article 10 (2) (b) as follows: «*b) software, including software updates or upgrades for the expected product lifetime or for a period of five years after the placing on the market or putting into service, whichever is shorter;*». If approved, this amendment would weaken the provision under paragraph 2, already characterised by a limited potential impact.

bad for society in general since it does not consider the case where the defendant was aware of a defect which, because of the gaps in the bureaucratic system of public controls (or the controls delegated to private companies), does not prevent the product to formally comply with mandatory regulations. This rule does not also take into account that mandatory regulations are often influenced by manufacturers.

197. The only coherent consequence with the provision confirmed by the Commission's "PLD Proposal" - exemption from liability in the case of conformity with mandatory rules - and the declared aim of providing protection to victims should be the joint and several liability of the manufacturer and the public authority, or, as a secondary option, the shift of the same regime of liability under the "PLD Proposal" from the manufacturer to the public authority. Leaving the aggrieved parties to face a denial of compensation based on this exemption of liability without any alternative solution would be against the protection of the rights that the "PLD Proposal" aims to grant to the individuals. Consequently, in the future it would be desirable to develop harmonized minimum rules concerning the liability of public authorities that some Member States already developed.

198. Finally, as to Article 10 (1) (d) the "12.11.2023 Parliament's PLD version" proposes to subject the exemption from liability based on conformity with «*legal requirements*» (instead of "mandatory rules") to the condition that «*the economic operator exercised all reasonable due care required in the circumstances*»: even though this scenario brings into the judicial assessment's orbit the economic operator's fault in order to see whether the exemption applies or not[57], this proposed amendment is extremely positive since, if approved, it would limit most, if not all, of the negative features outlined above in relation to this defence, this also in the light of the risks posed by new technologies and AI systems.

199. Also, extremely problematic remains the cause of exemption for the so-called "development risk defence" provided by Article 7 (e) of the 1985 PLD and by Article 10 (1) (e) of the "PLD Proposal"[58].

200. It is understandable that the protection of victims must not come at the price of hampering technological development of products in general and now of AI systems. Nevertheless, the rule as it is and as has been redrafted by the Commission in its proposal needs to be revised as well as completed with new scenarios (for example, the institution of a compensation fund).

201. Having said this, we agree with the proposed addition of the adjective "objective" to the reference to "state of scientific and technical knowledge": it makes it clear that "subjective knowledge" is not relevant for the purposes of exemption from liability.

202. On the contrary, first we disagree with this rule, as proposed by the Commission, where it does not consider, like it is also partially the case in relation to Article 10 (1) (c), situations like, for example, the case where the defect was caused by an update[59], as well as the case where the defect occurred after the moments made relevant by this rule, but the accident could have been prevented through a recall campaign or any other precautionary initiatives. To this last respect, experience shows that there are cases in which damage to individuals took place because a recall campaign failed to be completed in time and part of the final users were kept exposed to harm although the recall already in place.

[57] This further proves that the PLD regime is not intended as a pure strict liability regime.

[58] It should be noted that for unknow reasons only the manufacturer has access to the opportunity of escaping pliability, whilst, for example, the importer.

[59] Differently from the defence under Article 10 (1) (c), in relation to which paragraph 2 provides for the exclusion of software updates from its scope, as to the "development risk defence" there is not any similar provision, hence the producer would be exempted from liability by proving that the defect occurred because of a subsequent update.

203. The “12.11.2023 Parliament’s PLD version”, where it adds the reference to «*the last update supplied under the control of the manufacturer*», only rectifies the lack of any consideration of subsequent updates of the product, but not the other gaps above outlined. Moreover, the proposed amendment exonerates the manufacturer from any liability in relation to updates not supplied under its control: this may exempt from liability a manufacturer in spite of its awareness of the defect at the time of the update carried out by a third economic operator or following this update.

204. Secondly, we oppose Article 10 (1) (e), as also amended by the “12.11.2023 Parliament’s PLD version”, for the reason, already outlined in relation to Article 10 (1) (c), that it does not fit in with the new technologies and AI systems. In particular, if one provides an AI system with the means of humans and/or even a non-human freedom of developing itself towards damaging levels, there should not be any reasons for excluding liability of the producer on the ground of the (un)predictability of such involution of the concerned system; in fact, the root of the damaging event has to be found within the producer’s choice to let the system able to cause harm to humans. In other words, as further developed in relation to the “AILD Proposal”, one may say that the defence under Article 10 (1) (e) and already present in the 1985 PLD goes against Issac Asimov’s three laws of robotics, first that a robot shall not harm a human, or by inaction allow a human to come to harm.

205. We appreciate that, in relation to above concerns, Recital 37 of the Commission’s “PLD Proposal” - not amended by the “12.11.2023 Parliament’s PLD version” - specifies that, «*since digital technologies allow manufacturers to exercise control beyond the moment of placing the product on the market or putting into service, manufacturers should remain liable for defectiveness that comes into being after that moment as a result of software or related services within their control, be it in the form of upgrades or updates or machine-learning algorithms. Such software or related services should be considered within the manufacturer’s control where they are supplied by that manufacturer or where that manufacturer authorises them or otherwise influences their supply by a third party*». Nevertheless, one may question whether this recital has to be construed as if the mere supply of an item driven by an AI system gives rise to the manufacturer’s control after the item is put on the market.

206. In relation to the difficulties that would arise with the application of the “development risk defence” to new technologies and AI systems it is worth reminding that the European Commission’s Expert Group on Liability and New Technologies – New Technologies Formation (“NTF”) suggested to disapply this defence in relation to such area of products: «*[14] The producer should be strictly liable for defects in emerging digital technologies even if said defects appear after the product was put into circulation, as long as the producer was still in control of updates to, or upgrades on, the technology. A development risk defence should not apply*».

207. The “PLD Proposal” is even more critical than the 1985 PLD, where, on one hand, Article 15 (b) PLD now in force provides that Member States may, by way of derogation from Article 7 (e) [*development risk defence*], exclude or limit this defence in their national rules implementing the Directive[60], whilst, on the other hand, the “PLD Proposal” does not include any provision that allows the Member States to opt for the exclusion of this defence, with the result that this defence will not be optional anymore. The removal of the optionality of the

[60] In particular, Article 15 (1) provides that: «*1. Each Member State may:* […] *(b) by way of derogation from Article 7 (e), maintain or* […] *provide* […] *that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered*».

defence strikes the balance against the victim's interests. A possible way to find a more balanced solution would be to add to the PLD Proposal a provision establishing an EU-wide compensation fund for persons injured by products which are not defective on the grounds of the "development risk defence".

208. Another critical point concerning Article 10 of the "PLD Proposal" is where the "12.11.2023 Parliament's PLD version" adds to Article 10 (1) a new case of exemption from liability in favour of micro or small software enterprises: «*(aa) in the case of a manufacturer of software that, at the time of the placing on the market of that software, the manufacturer was a microenterprise or a small enterprise, meaning an enterprise that, when assessed together with all of its partner enterprises and linked enterprises within the meaning of Article 3 of the Annex to Recommendation 2003/361/EC, if any, is a microenterprise as defined in Article 2(3) of that Annex or a small enterprise as defined in Article 2(2) of that Annex, provided that another economic operator is liable under this Directive for damage caused by that software*». We disagree with this exemption which brings unnecessary uncertainty to the determination of potential defendants and as well as discrimination among such enterprises depending on the commercial chain they are engaged with.

209. Finally, we disagree with Article 12 (2) of the "PLD Proposal" as amended by the "12.11.2023 Parliament's PLD version" stating that: «*The liability of an economic operator may be reduced or disallowed when the damage is caused both by the defectiveness of the product and by the fault of the injured person or any person for whom the injured person is responsible**, including when the injured person does not install updates or upgrades provided by the economic operator that would have mitigated the defect***»[61]. First of all, the injured person's contributory negligence which causes the damage together with the defectiveness of the product (hence the injured person's contribution is not the sole cause of the damage) should never give rise to the exclusion of the economic operator's liability; instead, it may only reduce in part the liability. Secondly, as amended by the "12.11.2023 Parliament's PLD version" (see the part of the sentence in bold), this rule would generate an obligation on the consumers to update or upgrade the product according to the economic operator's decisions and strategies, including financial goals, regarding the development of the product. The consumers would have not got any means to avoid or counterbalance this obligation in spite of the costs and impacts on daily life imposed by the updates/upgrades. At least, in order to mitigate the negative effects on consumers that may arise from the amendment proposed by the "12.11.2023 Parliament's PLD version" it should be added that only the updates and upgrades granted «***for free***» by the economic operator and «***easily accessible***» may be relevant for the purpose of Article 12.

III.7. Disclosure of evidence and the database on PLD case-law.

210. Article 8 of the "PLD Proposal" provides for the disclosure of evidence in favour of the victims. Furthermore, Article 9 («*Burden of proof*») (2) (a) establishes that the defectiveness of the product shall be presumed also where the defendant has failed to comply with an obligation to disclose relevant evidence at its disposal pursuant to Article 8 (1).

211. PEOPIL welcome these new scenarios added by the Proposal, but find that a much better rule – even though significantly improvable –addressing discovery and connected presumptions is the one under the "AILD Proposal"[62].

[61] In the same direction see also Recital 41 as amended by the "12.11.2023 Parliament's PLD version".
[62] See § ____ below.

212. For the reasons explained below in relation to the “AILD Proposal”, disclosure of evidence should be granted to victims also outside and before trial/court proceedings focused on compensation for damages, hence we cannot accept the amendment proposed to Article 8 – paragraph 4 b (new) – by the “12.11.2023 Parliament’s PLD version”, where it clarifies that the new provisions on disclosure of evidence should not affect pretrial disclosure if any («*4b. This Article does not affect national law relating to the pre-trial disclosure of evidence*»).

213. As to the database that shall contain, in an easily accessible and electronic format, judgments delivered by the national courts and the Court of Justice of the European Union in relation to proceedings launched pursuant to the PLD Directive as well as other relevant judgments on product liability (see Article 15, «*Transparency*», of the Commission’s “PLD Proposal” as amended by the “12.11.2023 Parliament’s PLD version”), we suggest to amend this article in order that the database should also publish national court orders and non-final judgments, since they are relevant too for reasons of transparency and proper information to the potential victims and potential claimants in relation to the risks they may be exposed and the rights they may have. Moreover, in some Member States final judgments may intervene after several years of litigation, hence with the risk that these judgments may be published when they are not any longer of any particular interest. Clearly, the database should indicate whether a judgment is final or not. Moreover, the database should also contain judgments by the ECtHR which is not mentioned by Article 15 of the “PLD Proposal”.

III. 8. Recourse among several liable persons.

214. Recital (1) of the “PLD Proposal” declares that its aim is not only to protect “consumers” or, more generally, “injured persons” «*against damage to health and property’ caused by defective products*»’, but also to remove «*divergences between the legal systems of Member States that may distort competition and affect the movement of goods within the internal market*». However, as regards the right of contribution or recourse it seems to forget this second aim since the Proposal, under the heading of Scope, excludes the regulation of recourse claims when Article 2 (3) (b) of the Proposal provides that: «*This Directive shall not effect:* [….] *(b) national rules concerning the right of contribution or recourse between two or more economic operators that are jointly and severally liable pursuant to Article 11 or in case where the damage is caused both by a defective product and by an act or omission of a third party as referred to in Article 12*».

215. Pursuant to this provision, liability of a plurality of persons and, accordingly, their respective right of contribution or recourse, may thus arise between economic operators (cf. Article 11 “PLD Proposal”) or between an economic operator and a “third party” (cf. Article 12 “PLD Proposal”).

216. In particular, we support the following basic ideas:

- although all European legal systems have similar regulations regarding solidary liability and recourse, differences in detail are many (for instance, as regards contribution of the costs incurred with the advanced payment; payment of interest for the advancement; how the internal shares are distributed; how insolvency of one debtor is redistributed among the others; how prescription and acts carried by one co-debtor affects the others, etc.); these and other differences give rise to an important fragmentation provided by national rules and then may create more or less favourable conditions for manufacturing or distributing goods in one country than in another and, in our case, may entail more or less difficulties to economic operators bringing their recourse claims; although it is understandable that the European Commission does not

want to ‘kick the hornet’s nest’ of the rather diverse and complicated national regulations on recourse between economic operators, the differences in some respects between the national rules regulating the recourse claims are, in our opinion, so important as to require some legislative action by the European Commission;

- it should be noted that the Proposal does not mention that the rules for disclosure of evidence and for rebuttable presumptions of defect and casualty, which are ‘alleviating’ devices aimed at facilitating victims’ claims are also applicable to economic operators who have paid more than their share and seek recourse or indemnity from the other solidary debtors; to keep a certain equality of arms, the Proposal should not provide for substantially different probatory rules for the liability of the economic operator who has compensated the victim and the liability of the other solidary operators from whom the paying economic operator is seeking contribution and provide that the alleviating devices established for victims should also be applied in favour of economic operators seeking contribution.

III.8.1. Liability of multiple economic operators.

217. As between economic operators, Article 11 of the “PLD Proposal” provides that: «*Member States shall ensure that where two or more economic operators are liable for the same damage pursuant to this Directive, they can be held liable jointly and severally*».

218. However, as in the current Directive (Article 5 PLD) the Proposal does not define what “same damage” means. Some European legal systems consider that damage is the same when the tortfeasors have caused by their concurrent act one single injury to the victim (indivisibility of the injury), whereas others seem to give more relevance to the factual causation of the damage by two or more concurrent causes that are either necessary or sufficient condition for the damage to arise (indivisibility of causation). Legal writing has pointed out that indivisibility, either of the injury or of causation, is not the best criterion to establish the identity of a damage and further criteria seem to be necessary. Among others, these criteria are the identity of the damaged person and the affected interest, the time and place where damage takes place, the degree of the adverse change, the degree of the damage as well as the type of its origin.

III.8.2. Liability of an economic operator when a third party is also liable.

219. When damage is caused both by an economic operator and a third party, the Directive cannot extend its scope to parties who are outside its realm. For this reason, it cannot provide for solidary liability between the economic operator and the third party and confines itself to provide that this circumstance does not reduce the liability of the economic operator, i.e., that the victim can claim full compensation from him.

220. As in Article 8 (1) of the current Directive, Article 12 («*Reduction of liability*») of the “PLD Proposal” provides that: «*1. Member States shall ensure that the liability of an economic operator is not reduced when the damage is caused both by the defectiveness of a product and by an act or omission of a third party*».

221. The fact that the Directive does not provide for solidary liability in these cases does not mean that solidary liability may not arise on different grounds according to national rules, which is the case in most legal systems. When a third party has intervened, the only concern of the Directive is that the economic operator who is liable according to the Directive cannot

pretend to reduce his liability on the grounds that a 'third party' is also liable. Since the foreign manufacturer is not included within the scope of the economic operators of the Directive, it is a third party, in the sense of Article 12 (1) of the "PLD Proposal" [Article 8 (1) PLD], and the importer into the EU who has paid damages to the injured person may bring a recourse claim according to national law.

222. A third party can also be a person for whom the economic operator has a duty to respond and for whom he can be held liable according to national norms that lay outside the scope of the Directive, as in the case of a principal for the acts of her auxiliary or a person who is totally alien to the relevant economic operator as, for instance, in the case of damage caused both by a defect in the ecosystem and a cyberattack.

III.9. <u>Limitation periods</u>.

<table>
<tr><th>Directive 85/374/EEC</th><th>PLD Proposal</th></tr>
<tr><td>Article 10</td><td>Article 14
Limitation Periods</td></tr>
<tr><td>1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and
the identity of the producer.
2. The laws of Member States regulating suspension or interruption of the limitation period shall not be affected by this Directive.</td><td rowspan="3">1. Member States shall ensure that a limitation period of 3 years applies to the initiating of proceedings for claiming compensation for damage falling within the scope of this Directive. The limitation period shall begin to run from the day on which the injured person became aware, or should reasonably have become aware, of all of the
following:
(a) the damage;
(b) the defectiveness;
(c) the identity of the relevant economic operator that can be held liable for the damage in accordance with Article 7.
The laws of Member States regulating suspension or interruption of the limitation period referred to in the first subparagraph shall not be affected by this Directive.
2. Member States shall ensure that the rights conferred upon the injured person pursuant to this Directive are extinguished upon the expiry of a limitation period of10 years from the date on which the actual defective product which caused the damage was placed on the market, put into service or substantially modified as referred to in Article 7(4), unless a claimant has, in the meantime, initiated
proceedings before a national court against an economic operator that can be held liable pursuant to Article 7.
3. By way of exception from paragraph 2, where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the rights</td></tr>
<tr><td>Article 11</td></tr>
<tr><td>Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.</td></tr>
</table>

	conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a limitation period of 15 years.

223. PEOPIL has always been dedicated to developing a fair uniform system on personal injury limitation law. Here we recall the PEOPIL *Proposal for a Regulation of the European Parliament and the Council concerning limitation in respect of personal injury and fatal accident claims in cross-border litigation*, drafted in 2006 which became an Annex to the Draft Report with recommendations to the Commission on limitation periods in cross-border disputes involving injuries and fatal accidents (2006/2014(INI))[63], and the PEOPIL *Proposal for a regulation of the European Parliament and the Council on limitation periods for compensation claims of victims of cross-border road traffic accidents in the European Union*, drafted in 2012.

224. Article 14 of the Commission's "PLD Proposal", regarding limitation periods, maintains the three-year prescription period and, sadly, the ten-year extinction period currently enshrined in Articles 10 and 11 PLD. However, Article 14 (3) of the Commission's "PLD Proposal" extends the extinction period from ten to fifteen years when the injured person has not been able to initiate a procedure within ten years due to the latency of a personal injury. This last time-limit of 15 years has been expanded to 30 years by the "12.11.2023 Parliament's PLD version" subject to the requirement that the injured person has exercised «*all due care*».

225. First of all, we consider that the ten-year extinction period under the 1985 PLD is totally inappropriate primarily in the case of latent damage, i.e., damage that is discoverable only long after the damaging event took place, with the result that even the long-stop period may occasionally have already lapsed before the victim has had the chance to bring the claim. This has been the case with asbestos-related diseases, such as asbestosis and mesothelioma, which have very long latency periods, but it can also be the case with personal injury caused by other substances. In this sense, a ten-year limitation period was called into question by the ECtHR judgment of 11 March 2014, *Howald Moor and Others v Switzerland*[64], in the context of the application the starting point for the limitation period applicable under Swiss law to victims of asbestos exposure. Although the Court stated that the rules on limitation periods pursue the legitimate aim of ensuring legal certainty, their systematic application to persons suffering from diseases that cannot be diagnosed until many years after the triggering events, may deprive these persons of the opportunity to assert their claims before the courts. Consequently, the Court found that the application of the limitation period had restricted the victims' access to a court pursuant to Article 6 (1) ECHR to the point of impairing the very essence of his right.

226. Moreover, the absolute time period of 10 years period – even if extended to 15 years or even 30 years – is even more inappropriate in relation to AI systems, given that an AI artefact/system may manifest its risks and effects for the safety of persons only after several years of "autonomous life".

227. One possible solution to these cases is to establish different long-stop periods for personal injury claims (without any distinction among latent and non-latent injuries or diseases), a solution that was adopted by the 2002 reform of the German Civil Code, which,

[63] European Parliament's Committee on Legal Affairs, Rapporteur: Diana Wallis.
[64] Cour Européenne des Droits de l'Homme, Deuxième Section, Affaire Howald Moor et Autres C. Suisse (Requêtes nos 52067/10 et 41072/11), Arrêt 11 mars 2014, at *www.bailii.org/eu/cases/ECHR/2014/257.html*.

by contrast to the regular 10-year long-stop period, provides for a thirty-year period for damages claims for the infringement of life, bodily integrity, health or liberty [§ 199 (2) BGB]. Another possible solution is to do away with the long-stop period in the case of personal injury, a solution that was adopted in the Netherlands in 2004 or in France in 2008 by an amendment of the French Civil Code, which now provides that the general long-stop period of twenty years does not apply, among other specific cases, to claims for personal injury.

228. As to these the above options, coherently with the policy of law and the rules supported by PEOPIL in the above proposals on limitation periods, we insist that long-stop limitation period should be deleted in relation to personal injuries and fatal accidents, in relation to both primary and secondary victims. This would not only avoid solutions contrary to the above *Howald Moor* ruling of the European Court of Human Rights, but would also be in line - in relation to personal injury and death cases - with the tradition in most European jurisdictions and the trend in some other parts of Europe against long-stop limitation periods, a tradition and a trend that point in the exact opposite direction of Article 14 of the “PLD Proposal”.

229. If there would not be any margin for the long-stop limitation period to be abolished, at least it should be extended to at least 30 years, as also suggested by the “Parliament AIL Proposal” in October 2020, even though in relation to personal injury/fatal accident damages caused by AI systems only[65], and by the “12.11.2023 Parliament’s PLD version” [see the proposed amendment to Article 14 (3) [66]]. Nevertheless, the limit of this long-stop limitation period, even if extended to 30 years, is that it refers to “latent injuries” only, hence to injuries or diseases that existed but remained hidden or concealed and did not develop or manifest at the time of the mechanical force or trauma that directly caused the injury. Consequently, this long-limitation period would not assist those claimants that are injured by the product after several years only because the defect negatively develops or becomes “active” in the long period only (this may be the case of an AI system acquiring damaging features after a considerable number of years).

230. We also do not agree with the Commission’s “PLD Proposal” and the “12.11.2023 Parliament’s PLD version” approaches to the longstop period in relation to its starting date (*dies a quo*).

231. Sadly, under all the versions the longstop still applies from the date of supply: “placing on the market” now, rather than the obvious definition of supplying the victim. This remains a date that a victim cannot know and is exclusively in the knowledge of the producer. This has been a barrier to bringing a claim swiftly in the past and is likely to remain so. It is assumed that the date of supply has been the placing into circulation to mirror the starting date from measuring the defectiveness of the product. However, it is wrong that the producer under the 1985 PLD, in particular the manufacturer should control the starting date of supply. It leads to the absurdity that one producer faces a ten-year period of liability whilst another a much shorter period by holding up the distribution of the product once put into circulation. This is particularly indefensible when one puts the victim into this scenario and reverses the time line.

[65] Clearly, it does not make any sense at all to limit such scenario to new artificially intelligent technologies as same issues of access to justice would be met, for example, by the victims of pharmaceutical products or of environmental damages.

[66] Partially anticipated by the European Parliament’s Draft Report dated 5 April 2023 that proposed to amend Article 14 (3) by expanding the secondo long stop period to 20 years instead of 15: «*3. By way of exception from paragraph 2, where an injured person has not been able to initiate proceedings within 10 years due to the latency of a personal injury, the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a limitation period of 20 years*».

232. The absurd position remains that the claimant must write to find out who the various candidates for “producer” is and what the date of supply is and then be at the mercy of the manner and way in which the manufacturer or their representatives should respond. It remains unclear as to why the date of supply (along with the identity of the various versions of the producer) should be in the control of the manufacturer particularly when it determines long stop limitation, and is not an easily understandable date such as the date that the consumer receives the product clearly is. This would not affect the starting date for measuring the date of defect.

233. Moreover, this gives rise to further issues whenever a manufacturer and an importer are both potential defendants: this does result in the potential for two long stop limitation dates, the date that the manufacturer puts the product into circulation and that of the importer. There is of course an argument over whether the transfer from the manufacturer to the importer constitutes putting into circulation. Once again this is an issue that would not arise if the definition of supply was changed to the date that the injured party receives the damaging product. It would also remove significant amounts of correspondence, costs and wasted costs as well as a layer of complexity which would probably defeat the consumer without expert representation.

234. In conclusion, we suggest that the relevant moment shall be the one when the consumer or the injured party receives the product or – in the case of a bystander – he/she is negatively affected by the product.

235. Furthermore, should the long-stop period be confirmed, not only the concept itself of “putting into circulation”, that is currently used by the 1985 PLD, should be revisited as already outlined by PEOPIL in September 2020, but also the notion of the “manufacturer’s control”, which the pending proposals put beside the former one, should be carefully reconsidered, this mainly in order to take into account that AI systems may change and be altered due to their “autonomous life” as created by the producer.

236. In particular, if linked to the moment when the product gets out of the manufacturer’s actual control, the long-stop limitation period could become an unjust barrier to access to justice. The reference - added by the “12.11.2023 Parliament’s PLD version” - to updates, upgrades and substantive modifications of the product under the manufacturer’s control does not entirely solve this issue[67].

237. We may envisage two different scenarios:

- products are altered by someone else other than the manufacturer without any sort of consent to this alternation by the latter; in this case it is this other person who has control, not the original manufacturer, so it makes sense that the original manufacturer is not held liable any longer;
- the defect is just the result of the product’s “autonomous life” created by the original producer; the injuring effects of this “autonomous life” may take place or become manifest while the product is not under the control of the manufacturer; nevertheless, if the product has an “autonomous (damaging) life” is because the manufacturer has created it with this feature, hence it should be irrelevant whether it manifest itself while under control of the manufacturer or later; if the damaging effects of this “autonomous life” are not attributable entirely to a third party or the injured party, the manufacturer should be liable for the damage even if it manifests itself long after the loss of control,

[67] We suggest that the distinction between substantive and non-substantive modifications should not be kept in relation to the issue of limitation periods.

hence with the *dies a quo* running from the knowledge of causation and the most relevant consequences of the damage.

238. Clearly, the extension of the long-stop period up to 30 years may limit the negative effects of references to the moment when the product was placed on the market and the manufacturer's control. However, as already pointed out above, the application of the long-period suggested by the "12.11.2023 Parliament's PLD version" remains restricted to "latent injuries" only, hence it may be incompatible with products developing themselves into injuring items after several years like AI systems.

239. Finally, it is somehow disappointing that the EU is missing this opportunity to correct some of the common problems that have plagued the directive. No justification is set out as to why those under the age of majority; and those protected parties should still have the long stop limitation period applied to them.

IV. <u>THE "AILD PROPOSAL"</u>.

240. PEOPIL confirm its appreciation of the EU Institutions' aim to achieve at the European Union level both an "ecosystem of excellence" and "ecosystem of trust" in relation to Artificial Intelligence, being this aim the core of the proposal for the Artificial Intelligence Act.

241. Most of the existing AI systems are already characterised by a certain degree of complexity, connectivity, opacity, vulnerability, the capacity of being modified through updates, the ability for self-learning and potential autonomy. All these features make it difficult to attribute infringements and damage caused by such systems to specific harmful actions and subjects: there is and will be a serious problem in relation to the attribution of liability, hence imputability of damages. This risk may increase in the future.

242. Moreover, AI systems are under unpredictable developments. For example, it is recent news that AI is able to generate images from thoughts, in practice by reading minds, a power that would be subject to countless number of potential misuses and violations. The medium and long-term future of such machines/systems is largely uncertain also in terms of dangers for individual and communities.

243. From various sides there is an increasing and alarming indication that AI systems pose and will generate considerable risks for individuals and society in all its aspects. Just to make an example on 18 July 2023 Mr António Guterres, the United Nations Secretary-General, expressed the following concerns[68]: «*The malicious use of AI systems for terrorist, criminal or state purposes could cause horrific levels of death and destruction, widespread trauma, and deep psychological damage on an unimaginable scale.* […] *Both military and non-military applications of AI could have very serious consequences for global peace and security. The advent of generative AI could be a defining moment for disinformation and hate speech –undermining truth, facts, and safety; adding a new dimension to the manipulation of human behaviour; and contributing to polarization and instability on a vast scale. Malfunctioning AI systems are another huge area of concern. And the interaction between AI and nuclear weapons, biotechnology, neurotechnology, and robotics is deeply alarming. Generative AI has enormous potential for good and evil at scale. Its creators themselves have warned that much bigger, potentially catastrophic and existential risks lie ahead*».

[68] See www.un.org/sg/en/content/sg/speeches/2023-07-18/secretary-generals-remarks-the-security-council-artificial-intelligence.

244. Furthermore, there are also environmental challenges and new scenarios for occupational/industrial diseases stemming out of AI systems. In particular, as to the first side AI systems are far from being "clean", neutral technologies, and will cause huge contamination/pollution of physical areas through extraction for raw materials. AI systems are said to be hugely "hungry" of energy and that widespread use of AI systems may further undermine already stressed attempts to facilitate the UN Framework Convention on Climate Change Paris Agreement 2015 (where the fundamental aim is to keep global increases in temperature as low as possible and well under 2 degrees C, striving for 1.5 degrees C). Moreover, as to the second side, AI systems also generate workplaces which are often very undermining of health. The occupational conditions of individual workers required to work with AI systems are a serious issue. It is easy to foresee occupational illnesses being generated when AI systems work "correctly" in the same way that manufacturing caused massive health problems following the industrial revolution. Among the various factors that will impact on workers' mental health we may mention the following ones: -) since AI systems often cannot work completely unassisted by humas and there is therefore a need for an army of "human-fuelled automation" (!), workplaces will be increasingly mechanised and humas expected to "fit in" with machines in terms of rate/pace of work; -) increasing atomisation of work tasks which will be less varied (the ones the AI cannot do) and will become monotonous, hence generating stress; -) increased surveillance. What will health costs be in relation to these ways Ai-dictated ways of working?

245. Accordingly, liabilities and compensation for damage caused by AI as well as the, public and private, insurances for such damage are all legal issues that need to be addressed in order to build up the incentives for avoiding accidents and grant protection to the persons affected by AI systems.

246. Clearly, in a globalised world where the digital dimension is without borders there would be the need for a set of global laws in order to effectively address such goals and protect present and future generations from the dangers of AI systems. Global laws and global enforcement of such regulations would be the only solution capable of building up efficient bulwarks against the negative developments of AI; in the absence of global laws there will always be enormous gaps making it extremely difficult, if not impossible, to prevent infringements and develop actual accountability. Unfortunately, the United Nations does not seem to have the chances to be successful in this path. It looks absolutely improbable that we will get to one or more international conventions shared by States that are on the frontline of the evolution of AI systems and/or are capable of developing efficient protection also in legal terms.

247. Having the EU law-maker addressing the dangers of AI, accountability and remedies will not be enough to protect individuals and communities. Nevertheless, that the EU Institutions are taking care of safety, liability and compensation issues in relation to AI systems remains a positive important development. PEOPIL appreciate the commitment that the Commission, the Parliament, the Council and other bodies of the EU law-making process are devoting to the subjects here under scrutiny.

248. While PEOPIL have a positive opinion in relation to the path and solutions taken by the AI Act, PEOPIL disagree with most of the legal scenarios and options that have been suggested until now by either the Commission (the "AILD Proposal") and the Parliament (the "Parliament AIL Proposal") in relation to liability and compensation. Indeed, with regard to producers, developers, providers, operators and users of AI systems higher standards of

liability and compensation for damages should be pursued by the EU institutions, this in the light of the high level of dangerousness of AI systems.

249. The "AILD Proposal", if approved as it is, will lead to increased litigation among private parties because it is unnecessarily complicated, and poorly regulates the imposition of burdens or obligations on third party defendants.

IV.1. Damages caused by artificial intelligence systems: the need for a legislative intervention at the EU level and the options (general rules or provisions area by area?).

250. One may find that the present body of EU law, particularly in the product liability area and transport fields (road, air, railway, maritime), already provides for a regulatory framework sufficiently managing liability and insurance issues concerning losses caused by "things" including, in the present and future perspectives, objects/systems that are and/or shall be driven by forms of AI.

251. Nevertheless, with the exception of some products, services and activities (airplanes, ships, cars, trains) and producers' liability, there is a clear lack of EU provisions providing uniform basic minimum rules on liability and insurance for accidents caused by the operation and use of potentially "dangerous things", including most of the known AI systems.

252. Since its first position in September 2020, PEOPIL has agreed that the development of minimum common rules addressing the accountability-liability and public and private, insurance for losses caused by AI systems should be pursued at the EU law level. Then leaving to national laws the provisions on compensation with the sole exception of general principles aiming at granting primary and secondary victims with full compensation in relation to both material and non-material (or non-pecuniary) damages[69].

253. In fact, the EU product liability regime under Directive 85/374/EEC does not as such fulfil all the needs arising from the vast range of accidents caused by AI artefacts/systems. Moreover, as explained above, this situation would be improved only partially by the "PLD Proposal", if and when adopted and depending on which would be the final rules coming out from the present debate.

254. First of all, neither Directive 85/374/EEC nor the above "PLD Proposal" address the liability of owners, operators and user of AI systems whenever they are not producers, nor these subjects' insurance coverage for the damages arising from AI systems. It should also consider where producers, providers, operators and users of AI systems are not based in the European Union or in Europe, as well as the said complexity and opacity of AI systems. These make it more difficult and costly to assess the producers' and operators' liability especially where the chances to sue them or their distributors in the Union are low.

255. The difficulties for victims, present also under the "PLD Proposal" if approved, in bringing claims against the producers/providers/operators of AI systems, in particular whenever they are located outside the European Union, make much more stringent the need to address the liability of operators and/or users and/or other subjects. This includes those who, under the future AI Act, will be called to authorise, supervise and certificate these systems, at a EU law level. This need emerges by also considering that typically cases of personal harm resulting from accidents occurring during the operation or use of AI in practice are and will be more easily attributable in a large majority, at least at a first examination, to

[69] See PEOPIL Response to the EU Consultation on artificial intelligence liability and insurance for personal injury and death damages caused by ai artefacts/systems (September 2020), available at *www.peopil.com*.

operators or users other than the producers. This is especially so, if the liability of this last category of potential defendants has to be dealt with on the ground of the defectiveness of the system.

256. As to the EU transport provisions: not all of them contain uniform liability regimes. For instance, the motor insurance directives covering road traffic accidents do not provide for uniform rules on owners' and/or drivers' liability such liability being still delegated to national laws and subject to significant divergences among Member States. Moreover, the motor insurance directives' regime is not capable of addressing mass-damages cases like the ones that may be caused by AI systems.

257. Furthermore, there may be cases where the redress obligations imposed on traditional actors [for example, air carriers under Regulation (EC) No 889/2002 of the European Parliament and of the Council of 13 May 2002 amending Council Regulation (EC) No 2027/97 on air carrier liability in the event of accidents] and/or the already existing compulsory insurances coverages [like the one provided by Regulation (EC) 785/2004 on insurance requirements for Air Carriers and Aircraft Operators which also apply to some types of drone and automated aircraft] are not sufficient to address fairly and justly – in terms of prevention of damage, the sanction of unlawful conduct and compensation - the issue of liability and insurance coverage for damage related to the use of AI artefacts.

258. In particular, present limits on compensation and/or minimum coverages associated with already mandatory insurance may not satisfactorily address the need for protection arising from the accidents caused by AI artefacts/systems.

259. There are also areas of potential accidents attributable to AI artefacts/systems that, apart from the (limited) scenario of producers' and distributors' liability, are not covered at all by the already existing EU laws (for example, robots operating outside automated vehicles, like mobile robots, domestic robots, industrial robots, drones, home automation means for the elderly and disabled, robots in medical services, etc.).

260. In fact, while some AI systems (like software and hardware for, full or partial, autonomous driving of vehicles) form part of other things in relation to which there are already legal provisions in place (for example, motor vehicles and airplanes fully or partially driven by AI systems), other machines, may operate in the environment without being fixed to one physical location (mobile robots, drones). Most of the latter artefacts are not covered by uniform rules on liability and/or insurance.

261. Clearly, there are relevant gaps within the EU law. How to fill such gaps having in mind that without global law on AI not all holes will be filled?

262. It should be noted that there are not any harmonized general rules on liability, compensation and insurance at the EU level. This is something that, positive or not, may jeopardise the construction of general rules for AI systems, being such systems present in a wide range of situations, covering many different areas. These give rise to liability rules for all AI systems would mean creating something similar to general clauses of liability: This is an extremely hard task.

263. Moreover, AI encompasses and will affect many different technologies, it can be present in various systems/artefacts and it intervenes in a wide range of situations. As already remarked upon, the expansion of AI is largely unpredictable; would a single set of rules, if feasible, be sufficient for all cases, or will it be necessary to create different sets of provisions area by area?

264. We may need to recognise that AI encompasses many different technologies and hence demands many different sets of rules.

265. Given the difficulty of addressing within one single liability regime and/or insurance system all Al artefacts one may reasonably think of enacting provisions in relation to specific AI objects/systems. However, we need mechanisms for international cooperation, to develop shared principles and standards and prevent a "race to the bottom". Above all, while we may not know exactly what is going to happen next in AI, we must begin to take appropriate precautionary action now.

266. Accordingly, it would be advisable to develop basic rules enabling coverage for most if not all the AI artefacts/systems, leaving to the future the provision of more specific schemes.

267. This approach seems to be exactly the one that characterises the direction taken by "AILD Proposal".

268. Nevertheless, the scope of the proposal adopted by the European Commission suffers from being too limited in comparison with the actual need to establish strong rules against the development, operation and use of AI systems with damaging effects[70].

269. In particular, as to this last remark about the restricted scope of the proposed directive, it should be noted that the "AILD Proposal" goes for a common set of general rules that aims at covering two profiles only: (a) the disclosure of evidence on high-risk AI systems to enable a claimant to substantiate a non-contractual fault-based civil law claim for damages; (b) the burden of proof in the case of non-contractual fault-based civil law claims brought before national courts for damages caused by an AI system. This approach seems to be too minimalistic as further illustrated below. Different from the "Parliament AIL Proposal", in the Commission's proposal the issue of liability is touched only partially; the public and/or private insurance coverage of the damages caused by AI systems is not addressed by the "AILD Proposal". This criticism is carried out in spite of the fact that, given the negative potentialities of most of the rules suggested by the pending proposals, one may conclude that a limited scope of EU intervention should be preferred to extensive new rules restricting the victims' rights to compensation.

270. PEOPIL believe that common general rules on liability and insurance (not on compensation for damages[71]) favourable to claimants (in terms of easing the accountability of the defendants), including the institution of a strict liability regime[72] and rules on limitation law, need to be considered.

271. Furthermore, PEOPIL aim at pushing for harmonization in relation to accidents to persons caused by AI not only in relation to the European Union, but also having in mind a broader notion of Europe including States belonging to the European Economic Area (EEA), including the United Kingdom, the European Free Trade Association and, more in general, the Council of Europe.

IV.2. Artificial Intelligence systems: the arguable notion under the "AILD Proposal".

272. Among PEOPIL's fundamental concerns in relation to the risks arising from the "digital world" there is the strong belief that AI artefacts/products/things/systems, including Internet of Things (IoT) and robotics technologies, are and must be regarded, at least for legal purposes, as mere "things": more precisely machines/systems combining algorithms, data and computing power.

[70] See below §§ _____.
[71] See ____.
[72] See ____.

273. Whatever is the future of such artefacts/systems, for the present time and at least for the next two decades PEOPIL would exclude any scenario which somehow personalises at a general level AI artefacts/robotics/systems or such as to ascribe legal personality to such things.

274. In particular, AI systems (for the purpose of the law to be conceived as mere "things") are sometimes called "intelligent agents"; in some cases, they are even designed to function in the absence of human intervention (hence they enjoy some level of artificial autonomy which is surely subject to future expansion). They also may be provided with the ability to use some sort of "ethical reasoning" in solving problems and making decisions. Nevertheless, these are all developments that - at least for the purposes of civil liability, compensation and insurance - do not authorize producers, developers, distributors, auditors, regulators, owners, operators, utilizers to deprive AI artefacts/systems of the need for human decision/control in respect of the safety of persons and protection of any fundamental right (the so-called "human-in-the-loop" or "HITL" requirement, under which the AI system should work on the ground of model requiring human interaction and finally human control or decision). At least, such persons, in relation to their role, should be accountable for any departure from the safe operation of AI systems which may arise from the increase of autonomous intelligence, the ability to conduct ethical reasoning or any form of artificial consciousness of such machines/systems.

275. Accordingly, PEOPIL recommend that, for at least the purposes of civil liability, insurance and compensation of damage caused by Artificial Intelligence artefacts/systems as well as in relation to the protection of fundamental human rights, these artefacts/systems independently from the level of sophistication they have gained or will develop, should be dealt with as mere things/objects without any sort of personality or autonomy independent from human control and, since control is not sufficient alone, human decision. This combination between decision and control by humans should remain a key factor in all future scenarios and any lack of control in fact should not exempt providers, operators and users (or, as recently put by the European Parliament, "deployers") from responsibility.

276. The "AILD Proposal", by referring to the notion provided by the future AI Act adheres to the above conceptual framework.

277. In particular, Article 2 (1) («*Definitions*») of the "AILD Proposal" defines the notion of "AI system" by referring to the definition provided by the future AI Act. This approach, as already anticipated in relation to the "PLD Proposal", is clearly the correct one since it shall avoid potential conflicts among different legislative sources of EU law on "AI systems".

278. Nevertheless, as to the future AI Act there are still considerable problematic issues pending also in relation to the definition itself of "AI systems".

279. Whilst there is no single definition of "artificial intelligence" which is generally accepted by the scientific community, with the AI Act the EU legislator is trying to develop a notion of AI for the purpose of regulating it. The debate about this legal definition is still going on since the AI Act, which will provide for such uniform definition, has not been approved yet at the time of completing this paper (January 2024) and there are different options on the table. One may doubt the possibility that politicians will get to a suitable solution.

280. The initial proposal by the European Commission opted for the following notion of "AI system": «*'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions,*

recommendations, or decisions influencing the environments they interact with» [Article 3 (1) – point 1, of the Commission's AI Act proposal].

281. On 14th June 2023, the MEPs adopted the "*Parliaments negotiating position on the AI Act*", which also contains a significantly different definition for AI: «*'artificial intelligence system' (AI system) means a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions, that influence physical or virtual environments*» [Article 3 (1) – point 1, of the Parliament's version][73].

282. A similar definition of "artificial intelligence" or "AI" has been recently provided by the US President "*Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*" (October 30, 2023)[74] on the ground of the meaning set forth in 15 U.S.C. 9401(3): «*machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action*».

283. PEOPIL agree that the future legal notion should be broad and open to future unpredictable developments. However, the above definitions are unsatisfactory to this respect.

284. More specifically, in line with the recommendations made by the Turin Bar Council in 2022[75], PEOPIL observe that:

- both references to "software" (by the Commission) and even more to "machine-base system" (by the Parliament) are too limited and may become extremely obsolete in a relative short term. Instead, reference should be made to "electronic data processing system", which at least represents the core of the functioning of any AI, independently of its support, which, just to make an example, one day may also be part of biological-neurological dimensions[76];

[73] It is worth reminding that just two years before this definition given by the European Parliament the same Institution, at Article 3 of the "Parliament AIL Proposal", advanced a different definition: «*(a) 'AI-system' means a system that is either software-based or embedded in hardware devices, and that displays behaviour simulating intelligence by, inter alia, collecting and processing data, analysing and interpreting its environment, and by taking action, with some degree of autonomy, to achieve specific goals; (b) 'autonomous' means an AI-system that operates by interpreting certain input and by using a set of pre-determined instructions, without being limited to such instructions, despite the system's behaviour being constrained by, and targeted at, fulfilling the goal it was given and other relevant design choices made by its developer*».

[74] https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/

[75] In particular, the Council of Turin Bar Association suggested to the European Parliament and the AI Act's rapporteur Mr Benifei the following definition: «*'Artificial Intelligence System' (AI system): an electronic data processing system developed, by way of example and not exhaustively, with one or more of the techniques and approaches listed in Annex I* [of the AI Act]*, which, by analysing a data flow, can, by acting in the physical or virtual dimension, in a fully or partially automated way, for one or more objectives defined by man and/or by the system itself, generate outputs such as, by way of example, contents, forecasts, recommendations or decisions that influence, directly or indirectly, the environments*».

[76] Alternatively, one may opt for the following approach, similarly broad as to the way of describing on which "ground" AI systems operate: « *'AI system' means a system developed with the use of any data, software, hardware, computer applications, tools or utilities, including all mathematical framework, that is capable of autonomously generating outputs such as contents, predictions, recommendations or decisions influencing, directly or indirectly, the environments they interact with, whether supplied for professional or private use, for payment or free of charge*». This definition has been developed among PEOPIL Tort Reform Group while drafting this paper.

- the closed link, under the Commission's initial proposal, between the definition and list of the techniques and approaches listed in Annex I of the future AI Act[77] also contributes to restricting the notion in question to realities that may dramatically change in the near future; one solution may be the deletion of such reference (as proposed in June 2023 by the European Parliament amending the original text drafted by the Commission) or the clarification that reference to Annex I is for example purposes only;
- under the Commission's proposal it is assumed that the AI system operates "for a given set of human-defined objectives"; clearly, it is entirely desirable that AI systems will act pursuing "human-defined objectives" only. However, the risk – extremely relevant also for the purposes of the liability and the right to compensation for damages caused by AI – is that the AI systems may in the future develop and define their own objectives. In any case it may happen that it will be extremely difficult to distinguish between the original (human) objectives and the one adhered to by the "intelligent thing". Parliament suggested deleting the reference to "human-defined objectives", whilst this is a suitable solution; however, it may also be an option to make clear that the AI system may also pursue their own objectives, which does not mean that this scenario is somehow acceptable and permitted; by the way PEOPIL oppose any development that would lead AI systems to grow their own objectives;
- the Commission's proposal does not mention the autonomy of AI systems, which on the contrary is a fundamental feature of such systems; a system without at least a minimum level of autonomy is not AI;
- that the objectives may be explicit or implicit is something that should not need to be specified in the definition. On the contrary, that the influence can be either direct and indirect is a necessary clarification not only corresponding to what may happen in reality, but also essential for avoiding uncertainties as to material causation when establishing liabilities; both above versions of Article 3 (1), point 1, do not consider this issue;
- it should be clarified by the future AI Act that the expression "environment" is to be understood in the broadest and most inclusive possible meaning, in such a way as to embrace, by way of example, natural persons and legal persons, every natural element (fauna; flora; things; climate) as like any entity, dimension or space, whether they are terrestrial or extraterrestrial, of a physical, artificial, or digital type.

285. Accordingly, PEOPIL hope that the legal definition of an "AI system", which is now under scrutiny before the EU institutions, will be subject to further thoughts.

IV.3. <u>The limited scope of the "AILD Proposal": PEOPIL proposal for a broader objective and subjective scope</u>.

286. As already anticipated, the first main problem that PEOPIL envisage in relation to the "AILD Proposal", concerns the limited scope of the proposed rules, including the restriction

[77] Annex I of the Commission's proposal provides for the following techniques and approaches: (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; (c) Statistical approaches, Bayesian estimation, search and optimization methods. In June 2023 the Parliament proposed to delete Annex I.

of approximation to claims based on fault only where, in addition, the notion of fault is limited to a narrow notion of "human fault".

287. In particular, Article 1 («*Subject matter and scope*») together with Article 2 («*Definitions*») of the "AILD Proposal" clearly restricts the scope of the future common rules on liability for damages caused by AI systems by limiting the application of the proposed provisions:

- to high-risk AI systems only, this in relation to the provisions on the disclosure of evidence and the associated rebuttable presumption of non-compliance [78];
- to non-contractual fault-based civil law claims for compensation of damages[79];
- to damages caused (through the fault of a person[80]) by an output of an AI system or the failure of such a system to produce an output where such an output should have been produced;
- to the "procedural" purposes of easing the claimants' access to evidence and the assessment of liability (in particular, the "burden of proof"), in relation to the latter by providing two forms of rebuttable presumptions (the rebuttable presumption of non-compliance in relation to high-risk AI systems[81] and the rebuttable presumption of a causal link in the case of fault in relation to all AI systems, with internal distinctions depending on the level of risk associated to the system[82]).

288. Accordingly, and differently from the October 2020 "Parliament AIL Proposal", the "AILD Proposal" does not provide for a new EU liability regime (as was also suggested in 2019 by the Commission's Expert Group on Liability and New Technologies-New Technologies Formation), but, at least apparently, for "procedural rules" only[83] governing some aspects of the assessment of liability in court cases, hence when the claims have been reached the judicial stage.

289. PEOPIL stand for a significant expansion of the scope of the future directive in relation to all four points outlined above, besides the fact that, as it has said before, PEOPIL support the introduction of a strict liability regime[84].

IV.3.1. Why high-risk AI systems only in relation to disclosure of evidence and rebuttable presumption of non-compliance? Why different presumptions depending on this distinction?

290. The distinction between "high-risk systems" and all "other AI systems" is at the centre of all pending proposals, first of all the AI Act.

291. It should be taken into consideration that, at the time of writing and completing this position paper (January 2024), it is not clear yet which will be the final definition of an "high-risk system" adopted by the European Union within the AI Act. In particular, besides the cases

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[78] This limit, however, is contradicted by the proposal itself at Article 4 (5) expanding the application of the rebuttable presumption of causation to systems that are not high-risk where the national court considers it excessively difficult for the claimant to prove the causal link.
[79] See Article 1 (1) (a) and (b) and, in particular, (2).
[80] See below ____.
[81] See below ____.
[82] See below ____.
[83] See Recital 13: «*Other than in respect of the presumptions it lays down, this Directive does not harmonise national laws regarding which party has the burden of proof or which degree of certainty is required as regards the standard of proof*».
[84] See below ____.

where an AI system is intended to be used as a safety component of a product, or the AI system is itself a product, plus it is required to undergo a third-party conformity assessment related to risks for health and safety, with a view to the placing on the market or putting into service of that product, there is a contrast between the following positions. Whilst the Commission has proposed considering all systems listed in Annex III to the Act[85] as "high-risk systems" independently from the kind of rights/goods exposed to damages or the nature of the injured person (natural or legal). On the contrary the Parliament, on 14 June 2023, has opted to limit this third category of "high-risk systems" to only those AI systems falling under one or more of the critical areas and use cases referred to in Annex III: if posing «*a significant risk of harm to the health, safety or fundamental rights of natural persons*» or, in relation to the area of management and operation of critical infrastructure only, if posing a significant risk of harm to the environment.

292. The impression is that under the future AI Act the list of AI systems that may amount to "high-risk systems" may be quite limited indeed. If this is going to be confirmed, it will pose a concrete risk of not developing an effective protection of the future victims of AI in terms of liability and compensation for damages. Instead, the protection would be granted within a restricted area of cases only.

293. Nevertheless, one may accept that, subject to a broader notion of "high-risk systems", a distinction between these systems and "other systems" will be adopted as the basic scheme also in relation to and for the purpose of the establishment of a new liability regime. This is exactly the case of the approach followed by the "Parliament AIL Proposal" that distinguishes between high-risk systems (subject to a specific strict liability regime) and "other AI systems" (subject to a fault-based liability regime), even though also this proposal provides for a too much restricted notion of "high-risk system"[86].

294. On the contrary, as to the "AILD Proposal", which does not aim at creating a new liability regime, that this distinction should be kept in relation to "procedural rules" (the disclosure of evidence and the burden of proof on non-compliance and, to a certain extent, the rebuttable presumption of causation) does make less sense, if not any sense at all. This is even more true if the notion of "high-risk AI system" should be limited according to the AI Act as it is developing.

295. Consequently, should the limited scope of the objectives covered by the "AILD Proposal" be confirmed, PEOPIL suggest that reference to "high-risk systems" should be deleted from the future AILD: persons claiming for damages attributable to AI systems should benefit of the rights to disclosure of evidence as well as the facilitations in terms of presumption of causation independently from the classification of the system in relation to its potential seriousness of causing harms[87]. Instead, it would make sense to rely, according to

[85] This Annex includes the following critical areas: 1) biometric identification and categorisation of natural persons; 2) management and operation of critical infrastructure; 3) education and vocational training; 4) employment, workers management and access to self-employment; 5) access to and enjoyment of essential private services and public services and benefits; 6) law enforcement; 7) migration, asylum and border control management; 8) administration of justice and democratic processes.

[86] Unfortunately, also this Draft Regulation under Article 3 (c) provides for a restrictive notion of "high-risk systems": «*'high risk' means a significant potential in an autonomously operating AI-system to cause harm or damage to one or more persons in a manner that is random and goes beyond what can reasonably be expected; the significance of the potential depends on the interplay between the severity of possible harm or damage, the degree of autonomy of decision-making, the likelihood that the risk materializes and the manner and the context in which the AI-system is being used*».

[87] In this same direction see the clear suggestion by the European Data Protections Supervisor (EDPS)'s Opinion 42/2023, dated 11th October 2023, «*to extend the procedural safeguards provided for in Article 3 and 4 of the AILD Proposal,*

the AI Act general approach, on the distinction among high-risk AI systems and other AI systems in relation to the issue of the burden of proof/presumption of non-compliance, since the notion of "non-compliance" is strictly related to the duties established by the AI Act on the ground of the said distinction. In other words, because the AI Act establishes statutory duties which are different depending on the system's eve of risk and on the condition of the liable person (provider, user, or private user, i.e. person not using the AI system on the curse of a professional activity, etc.), one may accept that the rebuttable presence of non-compliance should be coherent with the differences linked to the specific statutory duties established by the AI Act for each of these cases: in most cases the possible infringement of these duties is what allows to presume fault.

296. Finally, if reference to "high-risk systems" should be kept in relation to disclosure of evidence and the burden of proof on rebuttable presumption of causation, than PEOPIL outline that "prohibited artificial intelligence practices" should also be included under the scope of the new directive, since it would not make any sense at all that the provisions under the AILD apply to damages caused by "high-risk systems" and not to the, even though too much limited by the future AI Act as it is developing, category of prohibited AI practices[88].

IV.3.2. Why "non-contractual + fault-based civil law"?

297. The claims relevant for the purposes of the future "AILD" are restricted to national liability regimes that are of an extracontractual nature and are based on "fault", meaning that the faulty conduct/omission of the defendant must be assessed in order to establish liability.

298. The recitals do not provide any particular explanation for limiting the scope of the approximation under the new directive to only national regimes based on non-contractual liability and centred on the assessment of the defendant's fault.

299. As to the reference to "extra-contractual liability", the "AILD Proposal" seems to ignore that in many situations that are relevant for the purpose of granting compensation to victims of AI systems there would be a contractual relationship between the providers/operators and the injured persons. In some jurisdictions in such situations the injured party may claim damages also (or only) on the ground of contractual liability, which is what generally happens whenever consumers, workers or, as to hospitals or similar environments, patients are injured by traditional things. To exclude these categories of claimants and claims from the scope of the "AILD Proposal" simply does not make any kind of sense, in particular if one considers that the Commission has opted for a minimum/minimalistic approach to harmonisation touching "procedural matters" only[89].

300. In relation to the restriction to national "fault-based liability" regimes the "AILD Proposal" does not consider that in some Member States many claims for damages that are likely to be caused by AI systems would be dealt with by applying particular forms of (non-

namely the disclosure of evidence and the presumption of causal link, to all cases of damages caused by an AI system, irrespective of its classification as high-risk or non-high-risk».

[88] As to this issue see also below ____.

[89] See Recitals 13 and 14.

absolute) strict liability[90], or by relying on concepts other than fault, i.e. incorrect performance of an obligation[91].

301. Against the above restrictions operated by the "AILD Proposal" one may also note that such specifications of the scope present a risk of considerable divergences in the application of the future directive, hence in the protection of victims. For example, in some jurisdictions a plaintiff may pursue his/her claim by relying simultaneously on two actions (one extracontractual, the second in contract), on the contrary in some other jurisdictions this is simply not possible. For example, whilst medical negligence cases are dealt with by some Member States via contractual liability, in other EU jurisdictions such claims, like many others, are subject to extracontractual regimes only. This means, in the scenario of approximation of national laws, that victims of similar damaging events will or shall not be subject to the directive depending on the Member State where the injury occurred.

302. PEOPIL believe that it does not make any sense to exclude from approximation of national laws contractual liability as well as liability regimes based on standards other than the fault. Why should there be any difference between, on one hand, granting a presumption of causality or the right to disclosure to a person injured by an "AI system" in violation of contractual duties and, on the other hand, protecting the same kind of person damaged in the context of a non-contractual relationship? Or, even though the damaging event occurs due to a contractual breach, having access, under the applicable law, to an action in tort only?

IV.3.3. The notion of "damage": any restriction?

303. By defining the notion of a "claim for damages" Article 2 (5) («*Definitions*») provides that the damage relevant for the purposes of the proposed directive should be «*caused by an output of an AI system or the failure of such a system to produce an output where such an output should have been produced*». This sentence may be construed in such a way that it does not add anything to the concept that the damage needs to be causally linked to an AI system. If this is the correct interpretation the definition should be redrafted in a much simpler way: "caused, entirely or partially, by an AI system".

IV.3.4. Immunities and use of AI for military purposes.

304. Finally, whilst under Article 2 («*Scope*») of the proposed AI Act makes clear that the future regulation should not apply to AI systems developed or used exclusively for military purposes (paragraph 3) nor to public authorities in a third country nor to international organisations where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States (paragraph 4)[92], under Article 1 («*Subject matter and scope*») of the "AILD Proposal" there is not any sign of such exclusions.

305. Accordingly, it seems that the category of claims covered by the future "AILD Proposal" may encompass also claims for damages caused by the use of AI for military

[90] For example, this would be the case of France (see the "*responsabilité du fait des choses*", custodian liability) and Italy (Articles 2050 and 2051 of the Italian Civil Code, respectively providing for "liability for dangerous activities" and "liability for things", hence for regimes "stricter" than the traditional one based on fault without reversals of the burden of proof).

[91] This is for example the case of the Italian "*inadempimento*".

[92] PEOPIL opposes the exclusion of national security, defence, and military purposes from the scope of the AI Act.

purposes, national security, defence, as well as claims against public authorities from a third country and international organisations.

306. PEOPIL, by also reminding that the European Parliament stressed that «*AI used for defence purposes should be responsible, equitable, traceable, reliable and governable*»[93] and by noting that liability is needed to secure responsibility, support the inclusion of such claims. In addition, it is against any form of immunities for the benefit of states (whether Member States or Third Countries), public authorities, international organisations, private companies acting on behalf of or delegated by public entities to pursue public functions or aims.

IV.4. <u>The categories of 'claimant' and "defendant" for the purposes of the "AILD".</u>

307. By reading conjunctively paragraphs (6) (notion of 'claimant') and (7) (definition of 'potential claimant') of Article 2 («*Definitions*») there should not be any doubt that both natural and legal persons injured by an AI system shall be allowed to bring their claims. PEOPIL welcome this approach, which reinforces our criticism[94] of the "PLD Proposal" that, in the opposite direction and in spite of also covering damages caused by AI, unreasonably restricts the category of 'claimants" to natural persons only.

308. As to the concept of "defendants", whilst the "PLD Proposal" is addressing the liability of the producers and other particular subjects, the "AILD Proposal" refers to any potential defendant, even though the focus in on providers, operators and users. In fact, under Article 2 (8) the category "defendant" seems to be extremely broad and should include all persons that may be liable for damages caused by an AI system, hence also persons ("users", or as indicated by the European Parliament, "deployers"[95]) using such AI for non-professional activities.

309. As already noted in relation to the "PLD Proposal"[96] there is a lack of consideration of the liability of subjects like the "conformity assessment body", "notified body", "market surveillance authority" and "national supervisory authority". Similarly, auditors and certification companies that may contribute to the availability of an AI system and the exposure of persons to it. This gap is manifest if one just considers the relevance attributed by the future AI Act to the above subjects and the "conformity assessment of high-risk AI systems". An assessment to which such systems, according to the AI Act, should be subject to prior to their placing on the market or putting into service. Anyway, nothing in the proposed AILD indicates that such subjects would not fall under the general category of the "defendants" relevant for the purposes of the future AILD. This imposes to review the proposed rules in the view of their application also to the above subjects.

IV.5. <u>Which rules for the approximation of liability for damages caused by AI systems? The approaches in favour of strict liability, the slippery notion of fault in relation to AI and the presumption of causation under the "AILD Proposal".</u>

[93] See point 94 of the *European Parliament resolution of 20 January 2021 on artificial intelligence: questions of interpretation and application of international law in so far as the EU is affected in the areas of civil and military uses and of state authority outside the scope of criminal justice* (2020/2013(INI)).

[94] See above ____.

[95] The original text proposed by the Commission of Article 3 (1) point 4 – referred to by Article 2 (4) of the "AILD Proposal – referred to the "user" («*any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity*»). The Parliament suggested to substitute the term "user" with "deployer", which does not appear to be any better than the term "user", clearly more explicit.

[96] See above ____.

310. As anticipated above, the "AILD Proposal" addresses the "burden of proof" issues with the purpose of facilitating claimants by way of "procedural rules"[97]. In particular, it provides, within the above limited scope, for two scenarios of rebuttable presumption, the first - in relation to high-risk AI systems only - of the "non-compliance" and the second of the "causal link in the case of fault".

311. A completely different approach could have been adopted by the Commission.

312. Firstly, it is worth reminding that in 2019 the Commission's Expert Group on Liability and New Technologies – New Technologies Formation indicated strict liability as the model to be adopted to address operators' liability irrespective of the level of the risks involved, whether high or non-high:

> **5. Operator's strict liability ([9]–[12])**
>
> **[9] Strict liability is an appropriate response to the risks posed by emerging digital technologies, if, for example, they are operated in non-private environments and may typically cause significant harm.**
>
> **[10] Strict liability should lie with the person who is in control of the risk connected with the operation of emerging digital technologies and who benefits from their operation (operator).**

313. In its *Report from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the safety and liability implications of Artificial Intelligence (AI), the Internet of Things and robotics* [dated 19 February 2020, COM(2020) 64 final] the Commission seemed to be directed towards the creation of a strict liability regime for the operation of AI applications with a specific risk profile[98]:

> For the operation of AI applications with a specific risk profile, the Commission is seeking views on whether and to what extent strict liability, as it exists in national laws for similar risks to which the public is exposed (for instance for operating motor vehicles, airplanes or nuclear power plants), may be needed in order to achieve effective compensation of possible victims. The Commission is also seeking views on coupling strict liability with a possible obligation to conclude available insurance, following the example of the Motor Insurance Directive, in order to ensure compensation irrespective of the liable person's solvency and to help reducing the costs of damage.
>
> For the operation of all other AI applications, which would constitute the large majority of AI applications, the Commission is reflecting whether the burden of proof concerning causation and fault needs to be adapted. In this respect, one of the issues flagged by the Report[62] from the New Technologies formation of the Expert Group on Liability and New Technologies is the situation when the potentially liable party has not logged the data relevant for assessing liability or is not willing to share them with the victim.

314. Secondly, in September 2022 there were already various options on the table towards strict liability approaches, like PEOPIL's previous recommendations posed in September 2020, that are now once more confirmed with this paper, and the "Parliament's AIL Proposal" (or "Draft Regulation").

[97] See in particular Recital 3, 4 and 5.
[98] Page 16 of the Report.

IV.5.1. PEOPIL's previous stand for a strict liability regime (confirmed!).

315. Liability rules that require from the claimants proof of a "defect"/fault/no-compliance/improper performance/etc., place injured persons in the extremely difficult position of assessing whether they can establish a potential claim where there are limits to access to the necessary information to establish a *prima facie* case, in relation to the operation of AI artefacts/systems.

316. In its position paper dated September 2020 PEOPIL fully agreed with the European Commission that «*Persons having suffered harm may not have effective access to the evidence that is necessary to build a case in court, for instance, and may have less effective redress possibilities compared to situations where the damage is caused by traditional technologies*» (White Paper, page 13).

317. Strict liability, here intended as a form of liability whereby the plaintiff has to prove, at least by way of presumptions, causation (in terms of implication of the damaging thing in the accident) and the defendant can escape liability by proving a fortuitous event, is an appropriate response to the risks posed by emerging digital technologies which carry an increased risk of harm to individuals (for example, AI driven robots in public spaces).

318. Accordingly, PEOPIL suggested in 2020 and still propose today, as an alternative to the minimal approach pursued by the "AILD Proposal", to create a new separate liability regime based on (non-absolute) strict liability designed for assessing the liability of owners, operators and/or users in relation to accidental harm arising from the operation and/or use of AI artefacts/systems.

319. In particular, PEOPIL still supports the following uniform basic rule for such a strict liability scheme: **anyone operating and/or using an AI artefact/system in his/her/its ownership or custody is liable for damages caused by it, unless he/she/it proves that the harm was the result of a fortuitous event**.

320. More specifically, under this proposed liability regime:

- the owner, the operator and the user of an AI system shall be liable for the acts or omissions of their servants, agents and any other person involved in the operation/use of the system;
- the injured third party, at his/her own choice, should be able to sue, individually and/or jointly and severally, both the owner and operator and/or the user if they are not the same person;
- the injured party, whether the primary victim or the secondary victim, should only have to prove the damage and the mere factual link between the harm and the AI artefact/system without any need to prove the underlying facts as to the conduct or operation of the AI artefact/system, the reasons or the dynamics, including those internal to the AI artefact/system, behind the occurrence of the accident; in other words, it should be sufficient to prove the "implication" of the AI artefact/system in the accident; then it would be up to the defendant to prove a "fortuitous event";
- a "fortuitous event" is a human or natural intervening event which, at the time of the accident, could not have been foreseen and prevented by the owner and/or the operator/user of the damaging AI system in spite of the adoption of all measures to avoid the damaging event taking place; however, if there is no valid explanation, external to the AI artefact/systems, for the accident, the defendant shall remain liable even though he can demonstrate the adoption of all measures to avoid the damaging event; accordingly, the mere absence of the negligence or other wrongful

act or omission of the owner or the operator/user or their servants or agents is not sufficient to exclude their liability whenever it is not possible to exclude, under the "more probable then not" standard, that the AI system has caused or contributed to the harm even though the reasons for its involvement remains uncertain;

- liabilities arising from the design, construction, sale, maintenance, operation, certification, registration of the AI system incurred by any person involved in such activities, like producers, distributors, auditors, regulatory bodies, maintainers, repairers, etc., shall not exclude or limit the owner's or operator's or user's liability in relation to injured third parties; owners and/or operators/users should be able to sue, by way of recovery action or subrogated claim, for damages against the third party responsible person.

321. This strict liability scheme should apply to any AI system independently from its level of potential risk[99], this at least in relation to personal injury and death case if not to all other infringements of fundamental rights.

322. Such a scheme should not prejudice the application of pre-existing liability regimes such as, for example, the Product Liability Directive regime or the Regulation (EC) No 889/2002 on air carrier liability. Accordingly, for example, under this proposal it would remain possible for the victim of an air disaster to rely on the specific strict liability regime provided by Article 17 and 21 of Montreal Convention 1999.

323. In the absence of any specific rules on owners' and/or users' liability either under Regulation (EC) 785/2004 on insurance requirements for Air Carriers and Aircraft Operators and under Directive 2009/103/EC relating to insurance against civil liability in respect of the use of motor vehicles, the above regime could also apply to drones and driverless motor vehicles. This application to accidents caused by autonomous cars would also be justified by the circumstance that the right to bring a direct action against the insurer under Directive2009/103 is based - in conjunction with Regulation (EC) No 864/2007 on the law

[99] One may object that this proposal would imply that all AI-systems and all activities that are carried out with these systems entail a risk that is always high or at least high enough to trigger strict liability, and that this contradicts reality (not all AI-systems entail a high risk and when they do the gravity or seriousness of the risk also varies). It may also be objected that this approach would also be against what is going to be established in the AI Act, since it would rank all risks at the same level. On the contrary, one may note that it is not possible to predict the level of risk connected with most of AI systems. Moreover, it is true that the principle underlying strict liability regimes is that liability ought to result from the materialisation of a specific risk, which is linked either to a thing or an activity under the defendant's control, irrespective of any actual lack of care on his part, but this does not mean that a liability regime may not regulate activities or things that may entail different levels or different kinds of risk: nothing prevents a regime of this kind to address liability in relation to different levels of risks (as the ones outlined by the AI Act) as long as such activities or things can be dealt with together under the same logics in terms, firstly in terms of prevention (unilateral/bilateral) and control, but also in relation to other features concerning for example their nature or causation. Furthermore, there is not any doubt that AI systems, independently from the level of risk, present same characteristics even though with different extents: complexity, connectivity, opacity, vulnerability, the capacity of being modified through updates, the ability for self-learning and potential autonomy. In relation to these arguments see the Opinion 42/2023, dated 11th October 2023, by the European Data Protections Supervisor (EDPS) that go in the same direction: «*25. The EDPS considers that AI systems, which are not classified as "high-risk", nevertheless have the potential to significantly harm individuals, even if those systems are not deemed to pose the same level of risk to the society at large. Moreover, non-high-risk AI systems might be similarly complex and opaque ('black box'), hence the victims could face serious difficulties getting access to the necessary evidence in order to identify the potential fault. 26. The EDPS recalls that the stated purpose of the AILD Proposal is "to ensure that persons claiming compensation for damage caused to them by an AI system enjoy a level of protection equivalent to that enjoyed by persons claiming compensation for damage caused without the involvement of an AI system" 28. In view of the objective to create such levelplaying field, there is an even stronger argument not to differentiate between the individuals affected by AI systems based on the classification of the AI system in question as high-risk or non-high risk*».

applicable to non-contractual obligations («Rome II») - on the national liability system of the State where the accident occurred.

324. However, in relation to road traffic accidents, it seems advisable to limit the application of this proposed new regime to autonomous vehicles only (hence excluding dual use motor vehicles) and to accidents that involve and are attributable to driverless vehicles only. These two restrictions would avoid the application, with regard to the same road traffic accident, of different regimes of liability, one for driverless vehicles (according to the proposed liability regime) and one subject to "ordinary" liability (provided by the applicable national law) in relation to non-autonomous vehicles in cases where two vehicles are involved, one driverless and one not. As a consequence, in this scenario, the insurance system and direct action provided by Directive 2009/103/EC would operate on the basis of the new liability regime only in relation to autonomous vehicles and accidents involving only such vehicles. An alternative to this solution may consist of the development of uniform rules on vehicle owners' and drivers' liability for road traffic accidents including those ones caused by driverless motor vehicles; nevertheless, one may oppose this more general approach to harmonization by noting that there are still considerable divergences among Member States in relation to liability for road traffic accidents (some countries apply strict liability approaches, some other fault-based systems).

325. In the absence of EU uniform provisions applying to liability arising from medical services the above suggested new liability regime may also apply to care providers' or suppliers' liability for damages caused by "healthcare robots" and other AI devices/systems employed for the provisions of medical services.

326. The proposed liability regime should also be equipped with provisions on limitation time/prescription. As to this respect, first of all PEOPIL remind the existence of the «*European Parliament resolution with recommendations to the Commission on limitation periods in cross-border disputes involving personal injuries and fatal accidents*», 2006/2014(INI) which is still relevant for the present debates both in relation to the "AILD Proposal", totally lacking of any provision in relation to limitation periods, and the "PLD directive". As minimum provisions PEOPIL suggest again that the limitation period for introducing claims under the liability regime suggested above shall not be less than three years and should begin to run from the day on which the plaintiff became aware, or should reasonably have become fully aware, of the following facts: that the injury, loss or damage in question is significant and/or is attributable in whole or in part to the AI artefact/system giving rise to the liability of the defendant, and/or the identity of the defendant. These provisions on limitation period should also apply to the direct action which should be available against the insurer as suggested below. Moreover, as already noted in relation to the "PLD Proposal"[100], given the characteristics of AI systems and digital technologies, there should not be any absolute limitation period, but, if this one would be provided, it should be established in a period of at least 30 years.

IV.5.2. The approach followed by the "Parliament AILD Proposal".

327. The path to the introduction of a specific strict liability regime for damages caused by AI system has been considered also by the "Parliament AIL Proposal" in October 2020.

[100] See § ____ above.

328. In particular, the 2020 Draft Regulation by the Parliament provided for a dual system, one based on a strict-liability regime for high-risks AI systems, one based on a fault-based liability regime including a rebuttable presumption of fault.

329. As to the first regime, paragraph 1 of Article 4 («*Strict liability for high-risk AI-systems*») provides for the following rule: «*The operator of a high-risk AI-system shall be strictly liable for any harm or damage that was caused by a physical or virtual activity, device or process driven by that AI-system*».

330. The only defence mentioned in this context is "force majeure"[101]. However, Chapter IV, which applies to all basis of liability established in the Draft Regulation, also mentions contributory negligence (Article 10, Draft Regulation).

331. Article 4 (4) requires that, both the frontend and the backend operators of "high-risk" AI systems, underwrite compulsory insurance.

332. As to the "other AI-systems" not constituting "high-risk systems" Chapter III of the Draft Regulation provides for a particular fault-based liability under which the defendant's fault is presumed (see Article 8, «*Fault-based liability for other AI-systems*»).

333. Article 8 establishes what appears to be an appraised enumeration of causes for exoneration or defences. Accordingly, the operators can escape liability by proving that the AI-system was activated without their consent, and all reasonable and necessary measures to prevent such activation were taken. Also, by proving that have acted with due diligence in the selection of the AI-system suitable for the relevant tasks and skills, in putting it into operation, monitoring it and maintaining it and by installing all available updates. The operator is not liable in the case of force majeure, but he remains subsidiarily liable in the case of harm caused by a third party that interfered with the AI-system by modifying its functioning or its effects, if such third party is untraceable or impecunious. It is interesting that Article 8 (2) also provides that «*The operator shall not be able to escape liability by arguing that the harm or damage was caused by an autonomous activity, device or process driven by his or her AI-system*». It also established a duty of the producer of the system to cooperate both with the operator and the injured party by providing information that is necessary to establish liability.

334. As indicated by the Parliament, this scheme of fault-based liability should be governed by the national rules of the EU Members States as regards limitation periods and *quantum* of compensation (see Article 9), but should be subject to the same rules of apportionment of liability (Chapter IV) i.e., contributory negligence, solidary liability, and recourse (Articles from 10 to 12, Draft Regulation) that apply in the case of strict liability for high-risks AI-systems.

335. This dual system of strict-liability for high risks and a rebuttable presumption of fault for fault-based liability presents many shortcomings.

336. That "Parliament AIL Proposal" the strict liability regime is based on high risks that have to be listed in the future in the Annex to the Regulation' would not be any longer an issue since it would be possible to provide for a connection with the AI Act underway.

337. Secondly, this proposed system of liability aims at creating new actors (frontend and backend operators) who, in the case of high risks, would be hold truly strictly liable, i.e. with no need to require the existence of a defect; this may give rise to continuous situations of conflict with the provisions of the Product Liability Directive.

[101] In particular, see Article 4 (3): «*Operators of high-risk AI-systems shall not be able to exonerate themselves from liability by arguing that they acted with due diligence or that the harm or damage was caused by an autonomous activity, device or process driven by their AI-system. Operators shall not be held liable if the harm or damage was caused by force majeure*».

338. The proposal to introduce a strict liability regime for damage caused by AI systems is surely positive and, as already reminded above[102], PEOPIL supports it in the (different) terms already exposed. Nevertheless, the “Parliament AIL Proposal” accompanies the provision for strict liability with several restrictions that PEOPIL strongly reject.

339. In particular, Articles 5 and 6 of the Parliament’s Draft Regulation deal in detail with several aspects of *quantum* of damages which seem unacceptable. First, Article 5 (1) (a) sets a cap of two million Euros for death and personal injury, and Article (1) (b) a one million Euros cap in relation to property damage arising from a significant immaterial harm (emphasis added) that resulted in a verifiable economic loss or of damage caused to property[103]. To make things even worse, these maximum amounts are per accident, not per injured person since Article 5 (2) of the Draft Regulation establishes a pro-rata reduction rule in the cases of a plurality of victims.

340. In fact, these amounts are much lower than those provided by Article 9 of the motor insurance Directive 2009/103/EC[104], as amended by Directive (EU) 2021/2118[105], which in relation to personal injury and death provides for 1.3 million Euros per injured party with a limit of 6.45 million Euros per accident irrespective of the number of injured parties, and for material damages 1.3 million euros per accident. Additionally, under the MID system these are minimum amounts, that the Members States can extend, by contrast to the Draft Regulation, where they are maximum amounts.

341. By establishing caps to strict liability, the Draft Regulation does not offer a solution for most serious cases and since the caps for damages in the case of strict liability are lower than the cap established for motor vehicles, it produces the ridiculous paradox of protecting victims of autonomous vehicles less than victims of conventional ones.

342. There is not any valid explanation for such restrictions: if one considers that AI systems may cause damages on a very large scale involving hundreds of victims, then it is crystal clear that in the vast majority of cases the “Parliament AIL Proposal” would not grant any effective remedy to victims of AI systems.

343. Moreover, Article 6 («*Extent of compensation*») of the Draft Regulation refers to recoverable heads of loss, but does not mention non-pecuniary loss consequential of personal injury or death, which presently is the European common core and that in many European countries is the most substantial head of loss in the case of low-income victims. Unacceptably as well, the Draft Regulation links compensation to secondary victims for loss of earnings in the case of death of a primary victim to the existence of a “legal obligation to support”, which also runs against the trend experienced in many European countries over the last decades, which tends to take into account factual situations of support. It should also be noted that for cases other than personal injury and death (i.e. events giving rise to significant immaterial harm that results in a verifiable economic loss and the case of damage caused to property) the right to compensation is restricted by Article 6 (2) to the occurrence of harm to the health or

[102] See § IV.5.2.
[103] Recital 16 explains what this means in a rather confuse manner by saying that «*Significant im-material harm should be understood as meaning harm as a result of which the affected person suffers considerable detriment, an objective and demonstrable impairment of his or her per-sonal interests and an economic loss calculated having regard, for example, to annual average figures of past revenues and other relevant circumstances*».
[104] Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability.
[105] Directive (EU) 2021/2118 of the European Parliament and of the Council of 24 November 2021 amending Directive 2009/103/EC relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability.

the physical integrity of the affected person; in such case compensation includes (only?) the reimbursement of the costs of the related medical treatment as well as the payment for any pecuniary prejudice sustained as a result of the temporary suspension, reduction or permanent cessation of his or her earning capacity or the consequent, medically certified increase in his or her needs. Considering the magnitude of potential cases where AI systems may cause infringement of rights other than the right to health and the right to physical integrity, the approach taken by the Draft Regulation is absolutely restrictive. PEOPIL cannot accept such restrictions that not only are obsolete and purely pro-defendants rules, but are also indifferent to the reality of the damaging events that may be caused by AI systems, like for example damages to data.

344. Anyhow, the mysterious inclusion in the definition of "harm or damage" [Article 3 (i)] a "… significant immaterial harm that results in a verifiable economic loss" and the even more bizarre explanation saying that this "significant immaterial harm should be understood as meaning harm as a result of which the affected person suffers considerable detriment, an objective and demonstrable impairment of his or her personal interests and an economic loss…" (Recital 16) could only cause confusion and perplexity to most European legal operators used to distinguish between pecuniary and non-pecuniary-loss.

345. The only positive aspect of the said strict liability regime can be found in Article 7 of the Draft Regulation that distinguishes different limitation periods that in the case of personal injury is of thirty years from the date in which the harm occurred, and in the case of property damage or the verifiable economic loss resulting from the significant immaterial harm, ten years for the date that the property damage or loss occurred or thirty years from the date on which the operation of the high-risk AI-system that subsequently caused the property damage or the immaterial harm took place. Although none of these prescription periods is subject to the discovery rule since they start running independently from any consideration regarding actual or possible knowledge of the victims (differently from above PEOPIL proposal which provides for shorter limitation periods, but running from the claimants' actual or constructive knowledge[106]), these limitation periods are much longer than the ones provided by the 1985 PLD (as well as by "PLD Proposal") [107].

346. For all the above reasons, the Commission's abandonment of the path initiated by the Parliament's Draft Regulation Proposal should be applauded. However, not all ideas put forward by the Draft Regulation should be left aside (in particular, strict liability, compulsory insurance and 30 years limitation period are all valid suggestions deserving to be taken into consideration even though with some relevant amendments). Moreover, the "AILD Proposal", as already illustrated above in relation to its scope, does not escape criticisms and should be revised in all its parts with the exception of Article 4 that, as explained below, should be entirely rewritten.

IV.5.3. The approach followed by the "AILD Proposal": at least apparently no new liability regime, but minimum rules on evidence, burden of proof and presumptions based on "human fault"; the lack of a uniform cause of action.

347. Under Articles 3 («*Disclosure of evidence and rebuttable presumption of non-compliance*») and 4 («*Rebuttable presumption of a causal link in the case of fault*») the "AILD

[106] See point ____ above.

[107] The Draft Regulation does not deal with interruption or suspension of prescription and provided that they would be governed by the corresponding national rules.

Proposal" follows a completely different path: it rejects the idea of creating a new civil liability regime, based on strict liability logics, properly designed for damages caused by the provision/operation/use of AI systems; instead, at least from what comes out of the recitals, it opts for the introduction of "procedural rules" only on burden of proof and presumptions.

348. One may argue that provisions instituting burden of proof on the claimants in order to have access to presumptions of the causal link (or of the non-compliance to specific standards or of fault) and/or reversals of the burden of proof on the defendants have to be regarded to as merely "procedural rules". In fact, liability regimes, whether codified or not, are generally defined by the presence of rules not only providing for factors like the role of fault and the level of the standard of conduct in terms of the rigor of the precautionary actions imposed on the potential defendants, but indeed also by the burden of proof and the applicable presumptions. In some jurisdictions they are classified as "substantive rules", in some other States as "procedural rules". Regardless the issue whether the former or the latter classification is the correct one, it remains that these are key factors in configuring a liability regime.

349. By the way, our impression is that the Commission proposed not only "procedural rules" in relation to specific aspects of fault-based liability provisions, but instead a confused liability model based on fault (more specifically, as exposed above, grounded on "human fault"[108]), even though it did not develop it like it occurred in relation to defective product liability or tour operators' liability for package travels.

350. This seems to be confirmed by the Explanatory Memorandum to the proposal where the Commission explained that: «*EU citizens, consumer organizations and academic institutions strongly supported measures on the burden of proof and harmonising no-fault liability (referred to as 'strict liability') coupled with mandatory insurance. Businesses were more divided on the policy options, with differences depending in part on their size. Strict liability was considered disproportionate by the majority of business respondents. Harmonisation of the easing of the burden of proof gained more support, particularly among SMEs. However, businesses cautioned against a complete shift of the burden of proof. Therefore, the preferred policy option was developed and refined in light of feedback received from stakeholders throughout the impact assessment process to strike a balance between the needs expressed and concerns raised by all relevant stakeholder groups*».

351. In fact, the Commission excluded strict liability as an option and created a short set of rules that, if adopted, will cause more harm to injured persons than benefits.

352. PEOPIL definitively oppose this policy of law. The effective protection of health, life, personality and other fundamental rights also by means of accountability and remedies including compensation cannot be pursued through compromises between such rights and the economic goals/interests of a restricted number of stakeholders. Rights and their protection are not a matter for bargaining. Abandoning the path towards strict liability is no way a compromise, but a political choice in favour of potential defendants and a weaker protection of potential injured parties.

353. That Article 5 («*Evaluation and targeted review*») together with Recital 31 of the "AILD Proposal" leaves a door open to the future creation of no-fault liability rules for claims against the operator, as long as not already covered by other Union liability rules in particular Directive 85/374/EEC, combined with a mandatory insurance for the operation of certain AI systems, as suggested by the European Parliament, it is not enough to justify the above policy.

[108] See points _____ above.

According to Article 5 this would be subject to a review of the Directive within five years after the end of the transposition period. A process like this one is too much vague and uncertain. By the way, it could have been and still can be the opposite approach: firstly, the introduction of a strict liability regime subject to a subsequent review.

354. Against the approach followed by "AILD Proposal" it should also be outlined that:

- as a matter of procedural power, or vires, the "AILD Proposal" is *ultra vires* the EU treaty, which does not give the EU power to harmonise national procedural law, whether by reference to disclosure or to the burden of proof. The substance of the "AILD Proposal" is not limited to cross-border claims where there is an impediment to access to justice. The Proposal seeks to harmonise in relation to all claims in relation to AI, whether there is a cross-border element or not;
- secondly, where there has previously been harmonization in relation to the burden of proof, see for example the Race Discrimination Directive 2000/43/EC, that provision applied to an EU cause of action, namely the principle of equal treatment. In the present case, there is no provision for an EU cause of action. There is mere harmonization of national procedural rules in relation to the application of national civil liability law, or even something more (an embryonic "human fault based approach to liability") but without it grounded on a cause of action. This is unlawful and mission creep on the part of the EU.

355. Accordingly, PEOPIL call out the fundamental lack of logic to the desire to provide minimum protection to individual victims without providing for an EU cause of action, as identified and referred to under Option 2 at page 9 of the Explanatory Memorandum[109]. The EU has no power to intervene on a preliminary Option 1 basis. If, as PEOPIL believe given the risks arising from AI systems, there is sufficient basis for the EU to intervene on the grounds of legal fragmentation and lack of protection, and risk to fundamental rights to life and physical and mental integrity, then the only available option is to harmonise for actions across the single market, whether cross-border, or not, by way of the provision of an EU cause of action, which provides an equivalent cause of action (and equivalent level of protection) for non-PLD cases as the PLD does for product liability.

356. As a consequence, PEOPIL identify and promulgate the cause of action schematized above at § ______ as the legal basis for a EU intervention equivalent in terms of access to justice to the PLD as well as aligning with the standards of safety which the PLD requires.

357. Under this approach one may also opt for a reversal of the burden of proof in the terms equivalent to that proposed above by us for the future PLD[110]: standard under the AILD should

[109] It is worth reminding here that these were the options assessed by the Commission:

> **Policy option 1**: three measures to ease the burden of proof for victims trying to prove their liability claim.
>
> **Policy option 2**: the measures under option 1 + harmonising strict liability rules for AI use cases with a particular risk profile, coupled with a mandatory insurance.
>
> **Policy option 3**: a staged approach consisting of:
>
> – a first stage: the measures under option 1;
>
> – a second stage: a review mechanism to re-assess, in particular, the need for harmonising strict liability for AI use cases with a particular risk profile (possibly coupled with a mandatory insurance).

[110] See above …..

mirror the standard under the PLD, this at least in relation to providers, operators and professional users.

IV.5.4. The slippery notion of fault in relation to AI systems: the need for departure from fault to strict liability.

358. Undeniably, under the present "AILD Proposal" the future directive's rules on presumption of causation are centred around the fault-based liability approach to damages caused by AI systems. This is an extremely critical feature of this Proposal since in general terms reference to "fault" in relation to AI systems may not be appropriate, not only because in practice "fault" is referred to natural or legal entities (not things), but mainly because focus should be placed on the "wrongful behaviour" (activity/inactivity) of the damaging AI systems instead on the "humans-in-the-loop" behind them; in addition, the Commission conceived the notion of "fault" in a way that seems to be extremely critical, controversial being it narrow, anyway likely to cause uncertainty and increase the burdens on victims in terms of *onus probandi*.

359. The "fault" referred to by the "AILD Proposal" does not consist of an activity, action, omission, wrongful behaviour, incorrect performance, etc. directly attributable to the damaging AI system indifferently from the level of human intervention on the role played by the AI system in the causation chain. Instead, it has to be a "human fault", the fault of a person "in-the-loop" or even outside the loop (the supervisor): for the application of the directive the AI system must have caused the infringement through the fault of a person. The claimant will have to prove the particular fault of the – natural or legal – person behind the injuring AI system.

360. In fact, this reading of the Commission's proposal may be contradicted by Article 2 (5) («*Definitions*») that provides for a notion of "damage" (or harm) which seems to be indifferent to the role of the human control/decision-making in the causation process leading to the damaging event (the "human-in-the-loop" or "HITL" factor/requirement): the damage only needs to be «*caused by an output of an AI system or the failure of such a system to produce an output where such an output should have been produced*», this, at least apparently, independently from the remaining level of human intervention in the causation process. Accordingly, under this notion of "damage" it would not matter whether under the national liability regime the focus is on the objective performance, behaviour or fault of the AI system, or on the subjective conduct of the person controlling the system.

361. Nevertheless, Recital 15 expressly adds that «*this Directive should only cover claims for damages when the damage is caused by an output or the failure to produce an output by an AI system <u>through the fault of a person</u>, for example the provider or the user under [the AI Act]*». Evidently, here the proposal makes it manifest that it only applies to cases where fault - or by the way the wrongful behaviour giving rise to liability - is human[111], adding that – again at Recital 5 – the directive would not apply to "human fault" consisting of a "human assessment" followed by a human act or omission, while in such case the AI system only provided information or advice which was taken into account by the relevant human actor[112].

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[111] See also Recital 22: «*For the presumption of causality under this Directive to apply, the fault of the defendant should be established as a human act or omission which does not meet a duty of care under Union law or national law that is directly intended to protect against the damage that occurred*».

[112] This contributes to make the scope of the future directive narrower.

362. We acknowledge that talking about the direct "fault" of an AI system (without putting "human fault" in the front, or even in terms of "human fault" vs "AI fault") may sound extremely incorrect. In the context of the "AI revolution" we may have to accept that, whenever violations and losses are caused by an AI system, there is no need, firstly for claimants and then for judges, to search for a particular traditional "human fault" and provide evidence for it. If anything, the "human fault" should be automatically inferred from the objective wrongful behaviour (wrongful activity/inactivity) of the AI system, a behaviour which is sufficient for establishing the liability of the persons providing, operating or using such system, unless these defendants prove some exonerating circumstances.

363. In fact, it would also be possible to assume that, if an AI system causes harm to a person's right, this means that it was faulty programmed or allowed to operate in such a way to contravene to the Isaac Asimov's Three Laws of Robotics[113] that basically represent a clever evolution of the principle *neminem laedere* which is the core of all forms of extracontractual liability. In other words, under this scenario there would always be a "human fault" at the origin of any damage caused by an AI system, like an original sin. The ones who provide, operate and/or use AI systems accept the risk of this sin. Clearly, this original "human fault" is different from the one referred to by the "AILD Proposal" which seems to look at the notion of "human control", which, in our vision, if proved (for example, a "lack of control", a misuse, etc.), should, if anything, aggravate the position of the defendant and, as a possibility, give rise, under the head of moral damages, to an increase of the *quantum* for non-pecuniary damages.

364. Clearly, the idea of relating "fault" directly to the AI systems (even by conceiving it essentially as an objective "wrongful behaviour") and/or intending it as a sort of "original sin" are approaches that are extremely critical too, but it remains that building up the first brick of the approximation of national liability rules in relation to damages caused by AI systems by making reference to "fault" intended as "human fault" (lack of control, not meeting the conditions established by the AI Act for the risk management, etc.) is far from being ideal. Given the difficulties of proving "human fault" instead of the objective activity/inactivity of an AI system, this is not the correct approach to the problem of accountability of such systems. Surely, it does not fit the reality and the future of AI. The strict liability approach suits better the prejudicial dynamics of the AI systems.

365. The Commission's reference and approach to "fault" would also increase the level of litigation around the scope of the future directive as well as limit to the claimants' access to the facilitations promised by the directive in relation to disclosure of evidence and presumption of causation: there is a significant difference among proving the behaviour of a person behind the damaging AI system and proving the damaging activity/inactivity of the AI system, unless one may automatically infer the "fault by a person" from the activity/inactivity of the system (this case seems to be excluded by the Commission's approach).

366. Certainly, the "AILD Proposal" also leaves on the debating table the relevant question whether the notion of "fault" under the future directive need to be construed on a subjective dimension only (hence the operator/provider's subjective foreseeability has to be assessed for establishing liability) or it can encompass the second scenario focused on the objective

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[113] It is worth reminding here the three rules: 1. A robot may not injure a human being or allow a human to come to harm. 2. A robot must obey orders, unless they conflict with law number one. 3. A robot must protect its own existence, as long as those actions do not conflict with either the first or second law. Asimov once added a "Zeroth Law" - so named to continue the pattern where lower-numbered laws supersede the higher-numbered laws - stating that a robot must not harm humanity or, by inaction, allow humanity to come to harm.

wrongful behaviour in itself. The latter being extendable to the activity of AI systems without the need to distinguishing between the damaging activity and the "human factor" behind it.

367. Furthermore, the Commission's approach centred on the fault of the "human-in-the loop" may increase litigation since the issue of control may encourage all potential tortfeasors saying "not me", with or without blaming others.

368. In conclusion, it is also for all these reasons that we insist for complete revision of the original proposal towards a new cause of action based on strict liability, even though non-absolute.

IV.5.5. Behind the provision for a rebuttable presumption of a causal link in the case of fault: more hurdles for the victims of AI under the "AILD Proposal".

369. Article 4 of the "AILD Proposal" establishes a series of rules that are intended to alleviate the proof of causality under national liability regimes based on fault, this by introducing several rebuttable presumptions. The presumptions are closely intertwined to the breaches of duties provided by the future AI Act.

370. PEOPIL agree that because of the features of AI systems (complexity, autonomy and opacity, the so-called "black box" effect, etc.) there is the need to alleviate the burden of proof pending on the victims (firstly in relation to causation). PEOPIL totally disagrees with the approach taken by the Commission with the "AILD Proposal", which also goes in the opposite direction of the suggestions provided by the Expert Group on Liability and New Technologies - New Technologies Formation in 2019.

371. First of all, as already anticipated, we disagree with Article 4 because:

- its scope is limited and it completely lacks of a uniform cause of action (in other words, it does not provide for a proper liable regime like the PLD one[114]);
- instead of being centred on wrongful activities/inactivities of the AI systems generating damages, it is focused on "fault", a notion which, being it also conceived by the Commission in a restricted way (the fault of the "human-in-the-loop"), not only is in contrast with the functioning of AI systems[115], but anyway does not permit to properly address the claimants' problems with establishing liability in general and causation in relation to damages caused by AI[116].

372. Secondly, we disagree with the Commission's approach since, even if one accepts the limited scope of approximation (presumptions "only"), the proposed model of rebuttable presumption of causality (*rectius*, the suggested model of liability based on "human fault") puts the injured parties before several new burdens of proof and many hurdles. The difficulties for the claimants under Article 4 are increased instead of reduced, this comparing with what happens in relation to claims pursued under the general rules on extracontractual liability that can be found in the vast majority of the Member States[117].

373. This appears confirmed first by Article 4 (1) that, by targeting all potential defendants in general, provides that national courts shall presume a causal link between the defendant's fault and the output produced by the AI system of the failure of the AI system to produce and output, when cumulatively, the following conditions are met: (a) that the claimant has shown

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[114] See points ______ above.
[115] See points ______ above.
[116] See in the same direction also point 33 of the Opinion 42/2023 by the European Data Protections Supervisor (EDPS).
[117] We certainly agree with BEUC position paper (BEUC-X-2023-050 - 02/05/2023) where it notes that «*the presumption of causality comes with so many hurdles and costs that it will be almost impossible for the large majority of consumers to benefit from it*». Unfortunately, these will affect not only consumers but all individuals damaged by AI systems.

that the defendant or person for whom he is responsible (for example, an assistant or employee) has not fulfilled a certain duty of care[118], established by Union law or by national law, the purpose of which was protect from harm that has occurred; (b) that it is reasonably likely that the fault influenced the output or failure of output of the AI system, and (c) that the claimant has demonstrated that output or failure of out-put gave rise to the damage.

374. Basically, contrary to the expectations for a rule actually alleviating the claimant's burden of proof as to causation (this intended as the material/natural causal link between the AI system and the harm), under Article 4 (1) the relevant causal link is not the one between the AI system's activity and the damage (independently from the specific reason why the activity/inactivity got to become damaging), but the one between the "human fault" of the defendant and the output produced by the AI system or the failure of the AI system to produce an output. This peculiar notion of causation imposes on the claimants a need to provide specific evidence about the internal aspects/dynamics/mechanisms/behaviours of the damaging AI system with particular regard to the role played by the "human fault" in the process leading to the damage. Clearly, as made manifest by paragraph (1) (c), under the "AILD Proposal" the claimant is still subject to proving causation in its traditional form: the injured party that is bound to prove that «*the output produced by the AI system or the failure of the AI system to produce an output gave rise to the damage*». Accordingly, the traditional burden of proof on causation is not alleviated by the proposed scheme.

375. To make things even more difficult for the claimants Recital 15 of the "AILD Proposal", as already reminded[119], explains that the damage must be «*caused by an output or the failure to produce an output by an AI system through the fault of a person, for example the provider or the user under [the AI Act]*», but it excludes «*liability claims when the damage is caused by a human assessment followed by a human act or omission, while the AI system only provided information or advice which was taken into account by the relevant human actor*». Hence, the claimant is also required to distinguish, logically by supporting this with proper evidence, between the "human fault", that influenced the output or the lack of expected output of the AI system, and the "human fault" consisting of a wrongful assessment of the information/advice provided by the system.

376. In practical terms, under the model proposed by Article 4 (1) the claimant has to open the AI's "black-box" and understand what is inside it, this in order to have access to the rebuttable presumption of causation. Put before such a scenario, one may question whether the claimant who is able to satisfy, cumulatively, the three above conditions still actually need to rely on such presumption.

377. Apart from the fact that all these difficulties for the claimants arising from an indeed rigid and demanding fault-based approach to liability prove the need for a completely different approach (strict liability or, at least, a diverse solution in conceiving the distribution of the burden of proof and the requirements for presumptions). It is clear that Article 4 (1) does not ease the claimants' path to compensation: on the contrary, it puts them in a much more complicated scenario which does not seem in line with the purposes of the proposal itself, the goals provided by the European Commission's White Paper [«*On Artificial Intelligence – A European approach to excellence and trust*», COM(2020) 65 final] and the *Report from the*

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[118] Under Article 2 (9) of the proposal «*'duty of care' means a required standard of conduct, set by national or Union law, in order to avoid damage to legal interests recognised at national or Union law level, including life, physical integrity, property and the protection of fundamental rights*». Clearly, instead of "legal interests" it appears more correct to refer to "rights".

[119] See points _____ above.

European Commission to the European Parliament, the Council and the European Economic and Social Committee on the safety and liability implications of Artificial Intelligence (AI), the Internet of Things and robotics [COM(2020) 64 final], as well as with the recommendations provided by the Expert Group on Liability and New Technologies - New Technologies Formation in 2019 that not only suggested for the operators a form of strict liability[120], but also a completely different approach to presumptions in relation to causation[121].

378. Having noted this about the first paragraph of Article 4, this provision does not improve in its following paragraphs.

379. Absurdly, paragraph 4 provides that in the case of a claim for damages concerning a high-risk AI system, a national court shall not apply the presumption laid down in paragraph 1 where the defendant demonstrates that sufficient evidence and expertise is reasonably accessible for the claimant to prove the causal link mentioned in paragraph 1. Apart from the fact that "reasonably accessible" is not defined by the proposal[122] and this may generate relevant divergences among the Member States, it should be noted that sometime before the Commission's proposal it was outlined that the most problematic aspect of data made accessible by a claimant is that «*its interpretation and analysis might be extremely complicated and costly*»[123], this being for granted in relation to a non-specialised claimant. Moreover, a rule like this one would only increase the matters subject to litigation and the uncertainties concerning the claimant's management of the court proceedings.

380. Paragraphs (2) (3) and (5) of Article 4 add some relevant (but negative for the claimants) specifications in relation to (i) claims brought against the provider of a high-risk AI system or against a person subject to the provider's obligations under the AI Act and (ii) claims brought against the user of such high-risk AI systems. These specifications significantly increase the level of barriers (burden of proof) for the claimants to have access to the rebuttable presumption provided by the first paragraph.

381. In particular, according to Article 4 (2) in the case of a claim for damages against a provider of a high-risk AI system subject to the requirements laid down in the future AI Act or a person subject to the provider's obligations pursuant to the same AI Act, then in order to satisfy the condition of paragraph 1 (a), the complainant is also required to demonstrate that the provider or, where relevant, the person subject to the provider's obligations, failed to comply with any of the following requirements laid down by the AI act: (a) the AI system is a system which makes use of techniques involving the training of models with data and which was not developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in the AI Act; (b) the AI system was not designed and developed in a way that meets the transparency requirements laid down in the AI Act; (c) the AI system was not designed and developed in a way that allows for an effective oversight by natural persons during the period in which the AI system is in use pursuant to the AI Act; (d) the AI system was not designed and developed so as to achieve, in the light of its intended purpose, an appropriate level of accuracy, robustness and cybersecurity pursuant to the AI Act; or (e) the necessary corrective actions were not immediately taken to bring the AI system in conformity with the obligations laid down in the AI Act or to withdraw or recall the system, as appropriate, pursuant to the same AI Act.

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[120] See point _____ above.

[121] See points _____ below.

[122] See Recital 27.

[123] A. BERTOLINI, *Artificial Intelligence and Civil Liability*, Study requested by the JURI committee, July 2020, page 84.

382. According to Article 4 (3) in the case of a claim for damages against a user of a high-risk AI system subject, for the purpose of meeting the condition provided by paragraph 1, letter (a), the claimant also need to prove that the user: (a) did not comply with its obligations to use or monitor the AI system in accordance with the accompanying instructions of use or, where appropriate, suspend or interrupt its use pursuant to the AI Act; or (b) exposed the AI system to input data under its control which is not relevant in view of the system's intended purpose pursuant to the Act.

383. Article 4 (6) adds a further obstacle for the claimants in the case of claims for damages against defendants-users who made use of an AI system in the course of a personal, non-professional activity: the presumption laid down in paragraph 1 shall apply only if the claimant proves that the defendant materially interfered with the conditions of the operation of the AI system or the defendant was required and able to determine the conditions of operation of the AI system and failed to do so.

384. It is clear that the provisions under the above paragraphs of Article 4 increase the burdens of proof and the difficulties for the claimants, this also against the suggestions provided in 2019 by the Expert Group on Liability and New Technologies – New Technologies.

385. Even under the most traditional fault-based system of liability it would be unjust to ask claimants to prove most of all the above factors, this in order to have access not to a declaration of liability, but to a rebuttable presumption of a causal link only. In fact, in most Member States, principles like "*prima facie* evidence", "*res ipsa loquitur*" or "proximity to evidence" enable victims to shift the burden of proof of fault and/or causation to the defendants.

386. Conclusively, PEOPIL oppose Article 4 because, apart from any other objection, it does not facilitate the victims of AI systems with establishing causation whenever the applicable national law grants them compensation on the ground of fault-based liability only[124].

387. Article 4 is also affected by the following problems:

- what should happen with damages inflicted by the provision/operation/use of "prohibited AI systems" (as defined by Article 5 of the future AI Act) is not mentioned in this Article. The fact that an AI system is prohibited does not exclude the possibility that someone, in breach of this prohibition, may cause damage to others. As a minimum, should Article 4 remain as it was drafted by the Commission, the Proposal should mention the impact of prohibited AI systems on these rules on presumption and establish that damage caused by a prohibited AI system gives rise to a presumption of fault and causation, this in order to bring the case along the lines of the Proposal and to avoid establishing a specific case of strict liability;
- paragraph 5 states that in the case of a claim for damages concerning an AI system that, according to the future AI Act, is not a high-risk AI system, the presumption laid down in paragraph 1 shall only apply where the national court considers it excessively

[124] This is in line with the conclusions by the European Data Protections Supervisor (EDPS) in its Opinion 42/2023 (11th October 2023): «*33. The EDPS notes that despite the introduction of specific procedural safeguards such as disclosure of evidence and the rebuttable presumption of a causal link, aimed at alleviating the victims' burden of proof, the Proposed AILD would remain a fault-based liability regime, which means that victims would still have to prove the fault or negligence of the AI system provider, operator or user. Meeting such a requirement may be particularly difficult in the context of AI systems, where risks of manipulation, discrimination, and arbitrary decisions will be certainly occurring, even when the providers, operators and users have prima facie complied with their duty of care as defined by the proposed AI Act*».

difficult for the claimant to prove the causal link mentioned in paragraph 1. Clearly, there is not any reason why a discretionary power of the court to disapply excessive burdens of proof like the ones established by the first paragraph (as negatively integrated by the subsequent paragraphs) should not apply also in relation to high-risk AI systems. There are even more reasons why disapplication of excessive evidential burdens should take place in relation to high-risk systems. Secondly, if one may support such a discretionary power, this scenario should be detailed in order to limit the risk of unpredictability of the judicial use of such power, hence the risk of discriminations among victims[125];

- Article 3 (1) (2) of the future AI Act states that «*'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge*». The "PLD Proposal", that refers to AI systems too[126], concerns the liability of "economic operators" including the manufacturer of a product or component, the provider of a related service, the authorised representative, the importer, the fulfilment service provider and the distributor. Recital 12 of the "PLD Proposal" specifies that «*The developer or producer of software, including AI system providers within the meaning of [Regulation (EU) .../... (AI Act)], should be treated as a manufacturer*». Lastly, Article 1 (3) (b) of the "AILD Proposal" states that the directive shall not affect any rights which an injured person may have under national rules implementing Directive 85/374/EEC. In the light of this picture, one may doubt about the effective scope of application of Article 4 of the "AILD Proposal" in relation to the liability of providers of AI systems.

388. Finally, there is a further and indeed key negative aspect with Article 4 as a whole: there is a concrete risk that the future directive will increase divergencies among Member States. In particular, the adverse impact that Article 4 will have on the victims' claims in the national systems may vary to a large extent, and therefore against the Commission's aims for the approximation of domestic laws.

389. More specifically, Article 1 (3) (d), which is contradictory and is subject to different readings, may also be construed as providing that in respect of what is established by Articles 3 and 4 the directive shall affect the national rules determining how fault is defined and which party has the burden of proof[127]. This provision is followed by Article 1 (4) establishing that

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[125] This risk is not solved by Recital 28: «*The presumption of causality could also apply to AI systems that are not high-risk AI systems because there could be excessive difficulties of proof for the claimant. For example, such difficulties could be assessed in light of the characteristics of certain AI systems, such as autonomy and opacity, which render the explanation of the inner functioning of the AI system very difficult in practice, negatively affecting the ability of the claimant to prove the causal link between the fault of the defendant and the AI output. A national court should apply the presumption where the claimant is in an excessively difficult position to prove causation, since it is required to explain how the AI system was led by the human act or omission that constitutes fault to produce the output or the failure to produce an output which gave rise to the damage. However, the claimant should neither be required to explain the characteristics of the AI system concerned nor how these characteristics make it harder to establish the causal link*».

[126] See § ___ above.

[127] In fact, this provision seems to affirm the opposite of what is supposed above in the text: «*3. This Directive shall NOT affect:* [...] *(d) national rules determining which party has the burden of proof, which degree of certainty is required as regards the standard of proof, or how fault is defined, other than in respect of what is provided for in Articles 3 and 4*». Nevertheless, on the contrary, as done in the text, one my emphasise the sentence "other than in respect of what is provided for in Articles 3 and 4". Hence, the Commission says the directive will NOT affect national laws with the exception of what is stated by Articles 3 and 4. In is a matter if fact that the Commission's sentence is quite misleading: it says "no" with a "big but".

Member States may adopt or maintain national rules that are more favourable for claimants to substantiate a non-contractual civil law claim for damages caused by an AI system; nevertheless, this may take place provided that such national rules are compatible with Union law and given that there is a political attitude towards higher standards of victims' redress protection. According to this approach by the "AILD Proposal" it appears that this directive may lead to national law reforms of traditional fault-based liability regimes with negative impacts on claimants, this in particular in those Member States that are politically inclined towards the under protection of victims' rights to compensation. The risk that these national laws may be influenced by the directive in such a way that victims will face an increased level of difficulties in establishing liability of the concerned defendants (providers, operators, users) is actual. On the contrary, some other States with opposite policies of law may simply do nothing as their fault-based liability regimes are more favourable for claimants.

390. Accordingly, if approved as it is, there is a considerable risk that, apart from the negative impact on the victims' claims for damage compensation, the "AILD Proposal" will fail with its main goal of creating approximation of the national laws.

391. The *Opinion of the European Economic and Social Committee on 'Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)'*[128] seems to have realized this risk by noting that: «*1.3. The EESC recognises that a minimal harmonisation serves this objective best, but is wary of the risk of divergent interpretations by stakeholders involved in the development and supply chain and by judges. It therefore insists upon clear legal definitions and the need to further enhance the required expertise of those who will have to apply this new legislation across the EU with appropriate digital capacity. The Commission's ultimate goal should be to pursue and develop a liability scheme that is as uniform as possible in its application across the EU*»[129]. This invitation by the EESC should be seriously taken into consideration.

IV.5.6. Suggestions: options for re-drafting of Article 4.

392. The draft AILD is founded on the assertion that there is fragmentation of the Single market by reason of different liability rules in each Member State [entrenched one may observe by EU law, namely the Rome II Regulation]. However, having harmonized liability rules under the PLD, and having asserted that the rules in the AILD should be aligned and equivalent in protection for products under the PLD, which legislative measures taken together are considered to be a package, the Commission refuses to provide an equivalent liability rule for non-PLD cases.

393. PEOPIL call out the EU Institutions and assert in clear terms that the AILD is adopting a wrong approach by not harmonizing and providing a minimum legal standard in relation to liability rules. The draft AILD is not adapting liability rules (despite its title and the preamble); it is seeking to harmonize procedural rules in relation to the burden of proof and in relation to disclosure.

394. Accordingly, PEOPIL remind the approach to harmonization suggested above at points/§§ ______, based on a uniform autonomous strict liability scheme according to which, in order to have access to a rebuttable presumption of liability (not of causation only), claimants would be required to prove the material/natural causal link between the damage and

[128] Adopted at plenary on 24 January 2023.

[129] www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/artificial-intelligence-liability-directive.

the AI system's activity/inactivity, hence the involvement of the latter in the causative process. In other words, in order to have access to such a rebuttable presumption, the injured parties should only have to prove the damages they suffered/will sustain and the involvement of the accused AI system in the accident (without the need to specify the exact way the AI system contributed to the damaging event).

395. Nevertheless, should the "AILD Proposal"'s minimal approach to harmonization be maintained (hence, minimum rules on rebuttable presumption of causation and one of non-compliance only), these rules should be completely re-drafted.

396. A starting point for such a review of Article 4 may be the following rule proposed by the Expert Group on Liability and New Technologies- New Technologies Formation in 2019:

> **11. Burden of proving causation ([25]–[26])**
>
> **[25] As a general rule, the victim should continue to be required to prove what caused her harm.**
>
> **[26] Without prejudice to the reversal of the burden of proof proposed in [22] and [24](a), the burden of proving causation may be alleviated in light of the challenges of emerging digital technologies if a balancing of the following factors warrants doing so:**
>
> **(a) the likelihood that the technology at least contributed to the harm;**
>
> **(b) the likelihood that the harm was caused either by the technology or by some other cause within the same sphere;**
>
> **(c) the risk of a known defect within the technology, even though its actual causal impact is not self-evident;**
>
> **(d) the degree of ex-post traceability and intelligibility of processes within the technology that may have contributed to the cause (informational asymmetry);**
>
> **(e) the degree of ex-post accessibility and comprehensibility of data collected and generated by the technology**
>
> **(f) the kind and degree of harm potentially and actually caused.**

397. However, the above rule should be amended too, firstly where it puts the application of the rule entirely in the hands of judges without trying to contain their discretionary power.

398. Accordingly, as secondary alternatives to the establishment of a proper strict liability regime, we may hypostasize the following two options.

399. The **first option** is the following rule developed by our group from the one proposed by the Expert Group on Liability and New Technologies.

> 1. **National judges shall presume, for the purposes of applying civil liability rules to a claim for damages, the causal link between the activity or inactivity of the AI system and the damage occurred to the claimant, whenever based on the circumstances of the case it appears reasonably possible that the AI system contributed, even only partially, to the harm or at least was involved in the damaging event.**
> 2. **For the purpose of paragraph (1) the reasonable possibility of the causal link occurs whenever one or more of the following factors are present:**

a) the AI system, at least apparently, behaved differently from the activity or inactivity that could have been expected from it in conformity with the requirements provided by international law, European Union law, national law or, international, national or local, scientific-technical standards and practices;
b) the damaging event occurred to the claimant is among the ones that could have possibly arisen from the AI system or similar AI systems;
c) the damage is of a kind that international law, European Union law, national law or, international, national or local, scientific-technical standards and practices were meant to avoid;
d) there is not any evidence or there are gaps in the evidence about the compliance of the AI system with the requirements provided by international law, European Union law, national law or, international, national or local, scientific-technical standards and practices;
e) the ex-post traceability and intelligibility of processes related to the AI system is as such as to make it difficult if not impossible for the claimant to establish causation.

3. National judges shall presume, for the purposes of applying civil liability rules to a claim for damages, either in relation to the defendant and/or the AI systems itself the fault, wrongful behaviour or incorrect performance, whenever, based on the circumstances of the case and depending on the qualification of the defendant, one or more of the following factors are present:
a) any of the factors listed at paragraph 2 from (a) to (d) included;
b) the ex-post traceability and intelligibility of processes related to the AI system is as such as to make it difficult if not impossible for the claimant to establish the fault, the wrongful behaviour or the non-performance of an obligation arising out of international law, European Union law, national law or, international, national or local, scientific-technical standards and practices;
c) the damaging event is one of those that could have possibly been prevented by way of use or monitor the AI system in accordance with international law, European Union law, national law or, international, national or local, scientific-technical standards and practises, or, in the case of non-professional users, the accompanying instructions;
d) the AI system violated any of the rights granted by the Charter of Fundamental Rights of the European Union or by the European Convention on Human Rights and Fundamental Freedoms or any International Treaty or Convention signed by the European Union.

4. Where a defendant fails to comply with an order by a national court in a claim for damages to disclose or to preserve evidence at its disposal pursuant to Article 3 (1) or (2), a national court shall presume either the causal link referred to by paragraph (1) and the fault, wrongful behaviour or incorrect performance referred to by paragraph (3), this interpedently from the assessment of any of the factors listed by paragraphs (1), (2) and (3).

5. National judges shall presume, for the purposes of applying civil liability rules to a claim for damages, the liability of the defendant, whenever the

damage was caused by the provision, operation or use of prohibited AI system as defined by Article 5 of the [AI Act].

6. **The defendant shall have the right to rebut the presumptions laid down in paragraphs (1), (3), (4) and (5).**

400. We are aware that the above rule is extremely complex. A simpler approach (**second option**) may consist of adopting a rule similar to the one suggested by the "12.11.2023 Parliament's PLD version" amending Article 9 (4) (1) (a) and (b) of the "PLD Proposal":

A national court shall presume the non-compliance of the AI system with safety or other legal standards or the causal link between the AI system and the damage, or both, where, notwithstanding the disclosure of evidence in accordance with Article 3 and taking into account all relevant circumstances of the case:
(a) the national court considers that the claimant faces excessive difficulties, due to technical or scientific complexity to be able to prove the non-compliance of the AI system or the causal link between this system and the damage, or both; and
(b) the claimant establishes, on the basis of relevant evidence, that it is possible that the AI system contributed to the damage, and it is possible that the AI system did not comply with safety or other legal standards or that its non-compliance is a possible cause of the damage, or both.

V. <u>THE "PLD PROPOSAL" AND THE "AILD PROPOSAL": COMMON ISSUES</u>.

401. There are several scenarios for approximation of national laws in relation to products, new technologies and AI systems that are common to both proposals and can be examined conjunctively.

V.1. Disclosure of evidence and rebuttable presumptions.

402. Having access to evidence in order to safely pursue a claim against a producer or anyone potentially liable for a damage caused by an AI system is extremely difficult for an injured party. Disclosure of evidence is directly connected with the fundamental right to access to justice. Is this is properly addressed by the two proposals here under scrutiny?

403. Apart from the doubt whether the "AILD Proposal" legitimately addresses this issue (in the absence of a proper cause action as legal basis there is no justification for harmonization of matters of civil procedure), unfortunately, both proposals are not satisfactory, even though the "AILD Proposal" provides for a much better model than the one suggested by the "PLD Proposal". Clearly, it does not make any sense at all to have different rules for similar cases and needs: the two proposals should be redrafted in order to develop a single rule valid for both – in part overlapping – areas.

"PLD PROPOSAL"	"AILD PROPOSAL"
Article 8	Article 3

	Disclosure of evidence and rebuttable presumption of non-compliance
1. Member States shall ensure that national courts are empowered, upon request of an injured person claiming compensation for damage caused by a defective product ('the claimant') who has presented facts and evidence sufficient to support the plausibility of the claim for compensation, to order the defendant to disclose relevant evidence that is at its disposal. 2. Member States shall ensure that national courts limit the disclosure of evidence to what is necessary and proportionate to support a claim referred to in paragraph 1. 3. When determining whether the disclosure is proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation to the protection of confidential information and trade secrets within the meaning of Article 2, point 1, of Directive (EU) 2016/943. 4. Member States shall ensure that, where a defendant is ordered to disclose information that is a trade secret or an alleged trade secret, national courts are empowered, upon a duly reasoned request of a party or on their own initiative, to take the specific measures necessary to preserve the confidentiality of that information when it is used or referred to in the course of the legal proceedings.	1. Member States shall ensure that national courts are empowered, either upon the request of a potential claimant who has previously asked a provider, a person subject to the obligations of a provider pursuant to [Article 24 or Article 28(1) of the AI Act] or a user to disclose relevant evidence at its disposal about a specific high-risk AI system that is suspected of having caused damage, but was refused, or a claimant, to order the disclosure of such evidence from those persons. In support of that request, the potential claimant must present facts and evidence sufficient to support the plausibility of a claim for damages. 2. In the context of a claim for damages, the national court shall only order the disclosure of the evidence by one of the persons listed in paragraph 1, if the claimant has undertaken all proportionate attempts at gathering the relevant evidence from the defendant. 3. Member States shall ensure that national courts, upon the request of a claimant, are empowered to order specific measures to preserve the evidence mentioned in paragraph 1. 4. National courts shall limit the disclosure of evidence to that which is necessary and proportionate to support a potential claim or a claim for damages and the preservation to that which is necessary and proportionate to support such a claim for damages. In determining whether an order for the disclosure or preservation of evidence is proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation to the protection of trade secrets within the meaning of Article 2(1) of Directive (EU) 2016/943 and of confidential information, such as information related to public or national security. Member States shall ensure that, where the disclosure of a trade secret or alleged trade secret which the court has identified as confidential within the meaning of Article 9(1) of Directive (EU) 2016/943 is ordered, national courts are empowered, upon a duly reasoned request of a party or on their own initiative, to take

	specific measures necessary to preserve confidentiality when that evidence is used or referred to in legal proceedings. Member States shall also ensure that the person ordered to disclose or to preserve the evidence mentioned in paragraphs 1 or 2 has appropriate procedural remedies in response to such orders. 5. Where a defendant fails to comply with an order by a national court in a claim for damages to disclose or to preserve evidence at its disposal pursuant to paragraphs 1 or 2, a national court shall presume the defendant's non-compliance with a relevant duty of care, in particular in the circumstances referred to in Article 4(2) or (3), that the evidence requested was intended to prove for the purposes of the relevant claim for damages. The defendant shall have the right to rebut that presumption.

404. Article 3 of the "AILD Proposal" and Article 8 of the "PLD Proposal" introduce a mechanism regarding disclosure of evidence which to some extent in based on arts. 6 and 7 of the Directive 2004/48/EC on the enforcement of intellectual property rights130. The results of infringing the rules on discovery are similar in both cases. Thus, failure to comply with the order of the national court regarding disclosure of relevant information leads to a rebuttable presumption of non-compliance with the relevant duty of care [Article 3(5) of the "AILD Proposal"), which according to the different legal systems can be understood as fault or breach of a statutory duty and, in the case of the "PLD Proposal", to a rebuttable presumption of defectiveness [Article 9(2)(a) "PLD Proposal"]. However, there are some differences between these two texts that seem unjustified.

405. As is well known, the disclosure process contributes to effective enforcement, may prevent non-meritorious suits at an early stage and provides incentives to compliance with the AI Act. In many cases a potential claimant will not be able to decide whether to sue or not a potential defendant due to uncertainty about the availability of the required information. These reasons apply both to the AILD and the PLD Proposals, but whereas Article 3 (1) "AILD Proposal" refers to potential claimants Article 8 (1) "PLD Proposal" does not as it seems to restrict the discovery only to the court proceedings for claiming compensation for damage caused by a defective product[131].

406. In our opinion, both provisions should include the reference of "potential claimants", as is the case in Article 3 (1) of the "AILD Proposal", since court fees or deposits that are to be paid for a mere disclosure proceeding can be much lower than those that are required for filing a claim in court.

[130] Directive 2004/48/EC of the European Parliament and off the Council of 29 April 2004 on the enforcement of intellectual property rights, OJ L 195/16, 2.6.2004.

[131] See now the "12.11.2023 Parliament's PLD version" of Article 8 (1): «*Member States shall ensure that in proceedings for claiming compensation for damage caused by a defective product, at the request of a claimant who has presented facts and evidence sufficient to support the plausibility of the claim for …*».

407. More precisely, both proposals should:

- clearly institute an extra-judicial discovery procedure (or pre-court discovery proceedings or pre-trial disclosure of evidence) under which manufactures, providers, operators and users should be given a deadline of 30 days to get back to a reasoned request by a potential claimant for the disclosure of evidence and/or any relevant information;
- allow the potential claimant to institute, at the expense of the defendant, a special judicial procedure dedicated exclusively to the disclosure of evidence and/or any relevant information in the case of failure by the manufacturer, provider, operator or user to provide an answer or in case of, full or partial, denial of access to the request evidence/information;
- provide the claimants' right to the same disclosure also within the judicial proceedings issued for the compensation for damages.

408. Additionally, both provisions indicate that the evidence that should be disclosed is the relevant evidence at the disposal of the (potential) defendant. However, we consider that disclosure of evidence should not be confined to cases where relevant evidence is at the disposal the defendant, but should also extend to cases where the information should legally be at the defendant's disposal (i.e. according to what the AI Act, EU law or national law provide).

409. Another lack of symmetry between Article 3 (1) of the "AILD Proposal" and Article 8 of the "PLD Proposal" which, in our opinion, defies any explanation, refers to the preservation of evidence.

410. It is true, however, that Article 3 (1) of the "AILD Proposal" refers to high-risks and Article 8 of the "PLD Proposal" is not confined to high-risk AI-systems but applies to all AI systems and, in general terms, to all defective products. However, we consider that whenever the law sets in motion a disclosure system rules on preservation of evidence are important in all cases in order to ensure the effectiveness of the disclosure system. For these reasons, a specific provision empowering courts to order evidence preservation measures should be added to Article 8 "PLD Proposal", with an ensuing presumption of defect if the defendant fails to comply.

411. Article 3 (1) of the "AILD Proposal" does not mention what these measures may consist of, or what kind of measures can be adopted. Article 7 of the Directive 2004/48/EC on the enforcement of intellectual property rights offers a more explicit guidance which could be adapted to the needs of AI-systems and defective products[132]

412. Another difference is that, in order to obtain disclosure under Article 3 (1) of the "AILD Proposal", it is compulsory that the claimant has previously requested the defendant to disclose relevance evidence, while a claimant under the PLD does not need to make such a previous request [Article 8(1) "PLD Proposal"). As a result, claimants under the "PLD Proposal" do not need to have undertaken all proportionate attempts at gathering the relevant evidence from the defendant before a court order in a damages case (cf. art. 3(2) AILD Proposal).

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[132] Thus, for instance, Article 7 of the Directive 2004/48/EC, among other measures, provides that «[S]*uch measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto. Those measures shall be taken, if necessary, without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the right holder or where there is a demonstrable risk of evidence being destroyed*».

413. The application of both Article 8 and Article 3 should not be subject to claimants having to prove the plausibility of the claim. Disclosure of evidence should be ordered by national judges when the potential claimants provide evidence of damage and involvement of the product (or the AI system).

414. In the case of fault- based liability we see no reason to limit the rules on disclosure of evidence to 'high-risk' AI-systems [cf. Article 3 (1) "AILD Proposal"], a limitation which has no parallel in the case of defective products. Moreover, the challenges that AI-systems pose to the proof of the conditions of liability are not confined to AI-systems that entail such risks. These challenges are inherent to AI and depend on the complexity of technology used by the AI-system. Accordingly, Article 3 and the disclosure of evidence mechanism should apply to all AI systems, not only high-risk AI systems.

415. Under both articles/directives manufactures, providers, operators should be obliged to provide the disclosed information in a way that is accessible (e.g. machine-readable format) and understandable for legal operators and consumers. It would be helpful and would avoid unnecessary additional expenditure if all disclosure of evidence rules specify that information.

416. Finally, both articles should provide for the suspension of the running of limitation periods during the pending of the procedures provided by them. This provision would be of extreme importance in relation to claims with cross-border elements.

417. Summing up, the AILD seems more detailed in its requirements in several cases but we see no reasons for these differences and we consider that the texts should be harmonised.

V.2. Provisions on personal injury and death damages: which approach to harmonization?

418. Presently, there still does not exist a sufficiently well-established and common legal background to permit a general legislative intervention by the European Union legislature in respect of specific detailed provision for categories of recoverable loss, methods of assessment (including criteria for medico-legal evaluation), minimum levels of awards for general damages, secondary victims entitled to compensation, etc.

419. Accordingly, PEOPIL agree with both the approaches characterizing the "PLD Proposal" and the "AILD Proposal" that, differently from the "Parliament's AILD Proposal"[133], do not contain any uniform provisions on compensation for damages.

420. We also insist with the position already expressed in our previous position documents during the path that led to the Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations («Rome II»). At their choice, primary and secondary victims should be able to obtain compensation according to the law of the country of residence, whenever this Member State is seized with proceedings and if this law provides them with a higher safeguard than the one granted by the applicable foreign law.

421. In particular, we support a drastic reform of Article 4 (1) of «Rome II» by turning back to the reasonable rule the European Parliament once suggested during the works that brought to the adoption of «Rome II»: «*where the harmful event results in a claim for damages for*

[133] See § _____ above.

personal injuries, the non-contractual obligation shall be governed by the law of the victim's country of residence»[134].

422. More specifically, the final Report adopted by the European Parliament at first reading in 6 July 2005 (P6_TA-PROV(2005)0284) contained, as also suggested by the Rapporteur Diana Wallis, a specific rule for RTA claims involving damages to persons: «*In the case of personal injuries arising out of traffic accidents, however, and with a view to the motor insurance directive, the court seised and the liable driver's insurer shall, for the purposes of determining the type of claim for damages and calculating the quantum of the claim, apply the rules of the individual victim's place of habitual residence unless it would be inequitable to the victim to do so. With regard to liability, the applicable law shall be the law of the place where the accident occurred*» [Article 3 (2)][135].

423. Unfortunately, the European Commission opposed the Parliament's wise proposal and we ended up with the current Article 4 (1). However it remains undisputable that applying the law of the country of the victim's place of habitual residence for the purposes of determining recoverable losses as well as category of secondary victims entitled to claim and of assessing awards is a solution much more equitable and fair for the injured parties and even more practicable for insurers and courts[136].

424. It should also be considered that a rule like the one proposed by the European Parliament at first reading would not force national courts to contravene basic principles of their own legal order, and to face the possibility of discrimination among their citizens.

425. Having said this and coming back to the two proposals here under scrutiny, we believe that, as already anticipated in relation to the "PLD Proposal" there is a step forward that can be made towards harmonization of law of damages.

426. Any infringement of fundamental rights - firstly those protected by the Charter of the Fundamental Rights of the European Union and by the European Convention on Human Rights and Fundamental Freedoms - should give rise to full compensation for pecuniary and non-pecuniary rights, also irrespective of the possible occurrence of negative consequences on health or physical/mental integrity as well as without the need of proving impairments or mental situation medically assessed or assessable.

427. While some Member States already cover non-pecuniary losses (even when the infringements do not amount to violations of fundamental rights), uniform law is needed in order to guarantee in every jurisdiction full compensation to primary and secondary victims.

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[134] Draft report on the proposal for a regulation of the European Parliament and of the Council on the law applicable to non-contractual obligations ("Rome II")(COM(2003)0427 – C5 0338/2003 – 2003/0168(COD)) Committee on Legal Affairs 11 November 2004.

[135] Obviously this rule could be criticized for limiting its scope to road traffic accidents only: why should there be such a distinction between victims of road accidents and victims of other damaging events (as for example medical negligence cases or accidents at work)? Our proposal is to extend this rule to any possible personal injury and death case.

[136] The final Draft Report adopted by the European Parliament, as the previous versions prepared by the Rapporteur Diana Wallis, was clearly inspired by a general philosophy that perfectly meets both the need for an higher level of certainty in relation to applicable law in the area of torts and the need to avoid injustice to the victims of wrongful harms. In particular, the Draft Report's aim to maximize «*legal certainty while allowing courts to use their discretion in choosing the solution which best accords with the need to do justice to the victim and with the reasonable expectations of the parties*» was indeed appreciable. This approach does not reduce the margins for bringing proper justice to victims. We surely face a rule that enables victims in personal injury and fatal accident cases to be compensated by properly taking into consideration the concept of full and fair compensation operating in the country where they sustain the losses. This approach avoids or, at least, significantly reduces the risk of leaving victims without a compensation considerable as appropriate and satisfying in the light of the social and economic background of their habitual residence. Therefore the rule grants to victims an appreciable level of redress protection since persons injured are likely to receive at least the compensation they would receive if injured in their own country.

428. The EU institutions already paved the way to this landing: for instance, the new Package Travel Directive[137], the General Data Protection Regulation (GDPR)[138], the Directive on the Enforcement of Intellectual Property[139] and the Directive on the Protection of Trade Secrets[140] all cover non-material harms and non-pecuniary losses.

429. Moreover, there is now a long list of various precedents from the Court of Justice showing that it is now accepted that EU laws providing for compensation of damages should be construed as imposing awards for immaterial (or non-pecuniary) damages too.

430. In particular:

- as to the compensation due by insurance undertakers in relation to road traffic accident victims according to the Motor Insurance Directives see:
- *Haasová*, C-22/12, ECLI:EU:C:2013:692 with reference to the right to compensation of the partner and of the child for the loss of their beloved: «*Article 3(1) of Council Directive 72/166/EEC of 24 April 1972 on the approximation of the laws of the Member States relating to insurance against civil liability in respect of the use of motor vehicles, and to the enforcement of the obligation to insure against such liability, Article 1(1) and (2) of Second Council Directive 84/5/EEC of 30 December 1983* […]*, as amended by Directive 2005/14/EC of the European Parliament and of the Council of 11 May 2005, and Article 1(1) of Third Council Directive 90/232/EEC of 14 May 1990* […] *must be interpreted as meaning that compulsory insurance against civil liability in respect of the use of motor vehicles must cover compensation for non‑material damage suffered by the next of kin of the deceased victims of a road traffic accident, in so far as such compensation is provided for as part of the civil liability of the insured party under the national law applicable in the dispute in the main proceedings*»;
- *Drozdovs*, C-277/12, ECLI:EU:C:2013:685 in relation to the right to compensation of a child for the death of the parents: «*Article 3(1) of Council Directive 72/166/EEC of 24 April 1972 on the approximation of the laws of the Member States relating to insurance against civil liability in respect of the use of motor vehicles, and to the enforcement of the obligation to insure against such liability and Article 1(1) and (2) of Second Council Directive 84/5/EEC of 30 December 1983* […] *must be interpreted as meaning that compulsory insurance against civil liability in respect of the use of motor vehicles must cover compensation for non-material damage suffered by the next of kin of the deceased victims of a road traffic accident, in so far as such compensation is provided for as part of the civil liability of the insured party under the national law applicable in the dispute in the main proceedings*»;
- *Petillo*, C-371/12, ECLI:EU:C:2014:26, concerning a personal injury case: «*34 The notion of 'personal injuries' covers any type of damage, in so far as compensation for such damage is provided for as part of the civil liability of the insured under the national law applicable in the dispute, resulting from an injury to physical integrity, which includes both physical and psychological suffering (Haasová, paragraph 47, and Drozdovs, paragraph 38). 35 Consequently, non‑material damage, compensation*

[137] Recital 34 Package Travel Directive (2015/2302) covers "non-material damage, such as compensation for the loss of enjoyment of the trip or holiday".
[138] Article 82(1) General Data Protection Regulation (2016/679) covers "material and non-material damage".
[139] Recital 26 Directive on the enforcement of Intellectual Property (2004/48) covers "any moral prejudice caused to the rightholder"
[140] Recital 30 Directive on the protection of trade secrets (2016/943) covers "any moral prejudice caused to thetrade secret holder".

for which is provided for as part of the civil liability of the insured person under the national law applicable in the dispute, features among the types of damage in respect of which compensation must be provided in accordance with, inter alia, the First and Second Directives (Haasová, paragraph 50, and Drozdovs, paragraph 41)»;

- as to "ruined holidays" see *Simone Leitner*, C-168/00, ECLI:EU:C:2002:163: «*in connection with tourist holidays, compensation for non-material damage arising from the loss of enjoyment of the holiday is of particular importance to consumers*» (para. 22:);
- in relation with air disasters see *Walz*, C-63/09, ECLI:EU:C:2010:251, stating that (para. 29) «*the term 'damage', referred to in Chapter III of the Montreal Convention, must be construed as including both material and non‑material damage*» (the Montreal Convention does not expressly provide for the compensation of non-pecuniary losses); as a further example, in *Sousa Rodríguez*, C-83/10, ECLI:EU:C:2011:652, the Court of Justice, in relation to the compensation of passengers in the event of denied boarding, cancellation or long delay of flights, stated that «*the meaning of 'further compensation', used in Article 12 of Regulation No 261/2004, allows the national court to award compensation, under the conditions provided for by the Montreal Convention or national law, for damage, including non-material damage, arising from breach of a contract of carriage by air*» (para. 46);
- in relation with personal data breaches see the recent judgment *Österreichische Post*, C-300/21, ECLI:EU:C:2023:370, not only stating in favour of compensation for non-pecuniary loss arising from, but also clarifying that Article 82(1) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) «*must be interpreted as precluding a national rule or practice which makes compensation for non-material damage, within the meaning of that provision, subject to the condition that the damage suffered by the data subject has reached a certain degree of seriousness*»; moreover, see *Natsionalna agentsia za prihodite*, C-340/21, ECLI:EU:C:2023:986, stating that «*Article 82(1) of the GDPR must be interpreted as meaning that the fear experienced by a data subject with regard to a possible misuse of his or her personal data by third parties as a result of an infringement of that regulation is capable, in itself, of constituting 'non-material damage' within the meaning of that provision*».

431. The EU Courts have consistently interpreted Article 340 TFEU, para. 2, which states that «*in the case of non-contractual liability, the Union shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties*», as covering, as a matter of principle, not only pecuniary losses, but also non-pecuniary losses: see, as to the scenario under Article 340, the Opinion of Advocate General Wahl in *European Union v. Kendrion* (C-150/17 P, EU:C:2018:612, point 103).

432. Finally, in the Italian Presidency of the Council of Ministers v. BV (C-129/19, ECLI:EU:C:2020:566) the Grand Chamber of the Court of Justice has concluded that the interpretation of Article 12 (2) of Council Directive 2004/80/EC relating to compensation to crime victims imposes on Member States to grant an «*appropriate contribution to the reparation of the material and non-material harm suffered*».

433. The inclusion of non-pecuniary damages among the items, which must substantiate awards for personal injury and death, is consistent with the protection of immaterial rights, goods and values to be granted by EU law under the Charter of Fundamental Rights of the European Union.

434. Accordingly, any new law addressing liability and insurance for accidents caused by products and AI systems should properly make it clear that the Member States shall ensure that victims are compensated for non-material damages too.

435. That if strict liability regimes or rules are created there would be need for restrictions to compensation for damages it is a myth originated by potential serial defendants including insurance companies.

V.3. <u>The need for uniform provisions addressing insurance for damages caused by AI artefacts/systems</u>.

436. The "PLD Proposal" and the "AILD Proposal" are both lacking in provisions addressing the issue of insurances and funds.

VI.3.1. Mandatory insurance and right to direct action against the insurer.

437. PEOPIL recommend that producers, distributors, providers and economic operators shall be covered by adequate mandatory insurance.

438. PEOPIL also recommend that any operation/use of AI artefacts/systems which can accidentally cause personal injury or death should be subject to mandatory insurance according to EU uniform rules and minimum standards, similar to those applying for the use of motor vehicles. This new insurance scheme should apply to cases not already covered by other mandatory insurances (private or public), provided at EU level or national level, without prejudice to more favourable protection for victims.

439. We strongly support the provision of a direct right of action against the insurer by the injured third party or his relatives in the case of fatal accidents.

440. In particular, if the liability regime outlined above is introduced, it should be subject to such mandatory adequate/satisfactory accident insurance together with the victim's right to issue, at his/her own choice, a claim for damages not only against the person liable, but also directly against the insurer, the latter action being based on a system similar to the one provided by Directive 2009/103/EC relating to insurance against civil liability in respect of the use of motor vehicles.

441. As to the suggested compulsory insurance it is possible to distinguish between two scenarios: a) where the damaging AI artefact/system is employed within a regulated activity (for example: driving a car or managing airplanes or trains; in the case of a factory, employing a manipulating industrial robot) and such activity is already subject to private or public compulsory insurance, such insurance should apply or be extended to damages caused by the AI artefacts/systems, if they are not already covered; b) where the AI artefact/system is being operated in a private context (for example, teenagers flying drones or individuals using domestic robots) or outside a regulated activity subject to mandatory insurance, then such insurance should be made compulsory.

442. Nevertheless, in both scenarios the same minimum standards should apply. More precisely, just as for motor vehicles insurance, minimum levels of insurance cover should be required by EU law for owners and users as well as there should be limited defined circumstances when insurers can avoid cover.

443. Under this proposed uniform law, minimum levels of cover for AI artefacts/systems should be at least the same levels of cover required for motor vehicles by Directive 2009/103/EC and ultimately Directive (EU) 2021/2118 (without prejudice to Member States being able to provide for higher levels of cover), although PEOPIL believe that: -) the minimum amount of cover of EUR 1.3 million per victim for the case of personal injury is insufficient to adequately compensate victims suffering severe injuries; -) the current minimum amount of EUR 6.450 million per claim, whatever the number of victims, should be increased in relation to the protection of passengers (tragedies involving buses and coaches prove that the current minimum amounts of cover are insufficient to provide an acceptable level of compensation where a considerable number of passengers are injured or die).

444. As to either private contexts and regulated activities not subject to mandatory insurance, there are basically two options that would need to be further investigated: 1) the insurance should be made compulsory upon the sale of the AI artefact/system; as a consequence, the sale should include, as part of the price, mandatory life-time (that is for the life-time of the AI thing) insurance cover in relation to accident liability; in this case, this insurance should include cover for persons who receive the AI thing as a gift or acquire it by way of subsequent onward sale; 2) the owner of the AI artefact/system should be under the duty to undertake an insurance in order to operate and use the purchased AI. The first option is as such as granting that the AI artefact/system is actually insured as soon as it is put into circulation without requiring any further initiative by the owner or the user.

445. In both options above sale of AI artefact/system should include a procedure for the registration of the AI artefact/system (manufacturing number/identification number) and the identity of the producer/seller/owner/user/operator; each owner selling the AI artefact/system and each subsequent purchaser should be responsible for all above registrations. Moreover, under above option 1 the seller should also register the insurer. Under option 2 the first owner should take care of registering the insurer.

446. There is no particular need for EU harmonisation of rights of subrogation or apportionment of liability between the insurer and the person or persons liable for the accident (whether the manufacturer; owner; operator; repairer of the AI machine/system, or another party involved in the accident).

V.3.2. National body or fund for compensation in relation to cases where the risk development defence applies and accidents involving untraced or uninsured AI systems.

447. Just as for motor vehicles under Directive 2009/103/EC as amended by Directive (EU) 2021/2118, each Member State should establish a compensation body or fund responsible for providing compensation to injured parties in the cases of untraced or uninsured AI systems involved in an accident that have caused personal injury or death.

448. The case of insolvency of the liable party and its insurer, if any, should also be covered by the here proposed compensation body or fund, not only in relation to AI systems, but to all products, as also suggested by the "12.11.2023 Parliament's PLD version" that proposed to add Recital 29a: «*Where victims fail to obtain compensation because no economic operator is liable under this Directive or because the liable economic operators are insolvent or have ceased to exist, Member States should be able to use existing national sectorial compensation schemes or establish new ones under national law, which should not be funded by public revenues, to appropriately compensate injured persons who suffered damage caused by defective products*».

449. This body or fund should compensate the primary and secondary victims on the same grounds of liability applying to producers, providers, owners and users.

450. Damages to victims should be awarded by this body or fund according to the same national rules on damages compensation applying to the defendants under the future PDL and AILD. Nevertheless, the body's or fund's obligation may be limited to the minimum levels of cover applying to compulsory insurance schemes if any.

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